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No. ______ 06 15 [illegible] 15 2007

In The
Supreme Court of the United States

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ISRAEL BIO-ENGINEERING PROJECT,

Petitioner,

v.

AMGEN INC., IMMUNEX CORPORATION,
WYETH, WYETH PHARMACEUTICALS, INC.,
YEDA RESEARCH AND DEVELOPMENT
CO. LTD., INTER-LAB LTD., AND
SERONO INTERNATIONAL, S.A.,

Respondents.

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On Petition For A Writ Of Certiorari To The United States Court Of Appeals For The Federal Circuit

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PETITION FOR A WRIT OF CERTIORARI

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QUESTIONS PRESENTED

I. Whether this Court should resolve the conflict between its own precedent and the Federal Circuit's decision below on whether the assignment of "all rights, title and interest" conveys ownership of the whole United States patent, thus conferring standing to sue for patent infringement.

II. Whether this Court should resolve the conflict between the Federal Circuit's decision below creating an irrebuttable federal presumption of employee patent ownership and decades of circuit court precedent holding that state law governs employee ownership.

III. Whether this Court should review the Federal Circuit's decision below to resolve disputed evidence of contractual intent on summary judgment in conflict with this Court's precedent.

PARTIES TO THE PROCEEDINGS AND RULE 29.6 STATEMENT

There are no parties to the proceedings other than those listed in the caption.

Petitioner Israel Bio-Engineering Project is not a corporation and has no parent corporation or stock. No publicly held company owns 10 percent or more of its shares.

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PETITION FOR A WRIT OF CERTIORARI

Petitioner Israel Bio-Engineering Project ("IBEP") respectfully requests that this Court issue a Writ of Certiorari to review the judgment of the United States Court of Appeals for the Federal Circuit.

OPINIONS BELOW

The opinion of the United States Court of Appeals for the Federal Circuit is reported at 475 F.3d 1256 (App. 1-23.) The opinion of the United States District Court for the Central District of California is not reported. (App. 24-36.)

JURISDICTION

The judgment of United States Court of Appeals for the Federal Circuit was entered on January 31, 2007. On February 23, 2007, the court of appeals denied the Petitioner's timely petition for rehearing by the panel. The jurisdiction of this Court is proper under 28 U.S.C. § 1254(1).

STATUTORY AND FEDERAL RULES PROVISIONS INVOLVED

35 U.S.C. § 100(d): "The word 'patentee' includes not only the patentee to whom the patent was issued but also the successors in title to the patentee."

35 U.S.C. § 261: "Subject to the provisions of this title, patents shall have the attributes of personal property."

35 U.S.C. § 281: "A patentee shall have remedy by civil action for infringement of his patent."

Fed. R. Civ. P. 56(c): "The judgment sought shall be rendered forthwith if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law."

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INTRODUCTION

This case involves important issues of U.S. patent ownership and standing and meets all of the customary criteria for certiorari. *See* Sup. Ct. R. 10. First, the Federal Circuit's ruling squarely conflicts with long-standing precedent of this Court on patent assignments and ownership. More than a century ago, this Court ruled that a patent assignment that conveyed "all right, title and interest" to a patent conveyed "the whole title in the patent," giving the assignee standing to sue for infringement. *Waterman v. MacKenzie*, 138 U.S. 252, 261 (1891). The Federal Circuit's position that the identical language transferred only a fractional interest in the patent to IBEP, an investment partnership, flouts this century-old doctrine.

The Federal Circuit exacerbated its error by ignoring this Court's watershed decisions on the proper use of summary judgment by resolving disputed issues of contractual intent. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242 (1986); *Celotex Corp. v. Catrett*, 477 U.S. 317 (1986); *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574 (1986). Specifically, the Federal Circuit found

IBEP's evidence that it had indeed bargained for sole ownership of the whole patent "unpersuasive."

Second, the Federal Circuit ruling conflicts with decades of circuit court decisions holding that state law governs ownership of inventions in the employer/employee context. Ignoring the weight of precedent, the Federal Circuit improperly created an irrebuttable federal presumption of employee/inventor ownership, even though state law (in this case, the law of Israel) unequivocally transferred ownership of employee inventions to the employer. This issue was dispositive because the employer—Inter-Yeda, an Israeli research company—was bound by a contract that assigned ownership of "all rights, title and interest" in the patent covering the invention to IBEP.

Third, the Federal Circuit's ruling creates confusion and uncertainty in a matter of overriding importance. Suffice it to say that advances in biomedical research have led to longer, healthier lives for millions of people throughout the world. For example, Enbrel, the drug at issue here, treats the worst kind of rheumatoid arthritis. Drugs such as Enbrel would not be possible without the infusion of investment capital from entities such as IBEP willing to incur substantial risk. IBEP did not simply buy a portfolio of existing patent rights to license and enforce, but instead provided a source of desperately needed funds at a time in the early 1980s when investment capital was nonexistent in Israel. It is no exaggeration to say that without IBEP, there would be no Enbrel.

Investors and research companies require certainty in their contracts and assignments in order to underwrite highly risky research and development projects such as the one in this matter. Rachel Krevans, *The Evolving Role* *of Patents in the Biotechnology Industry*, Report of Bay Area Science and Innovation Consortium, p. 20 (June 2004) ("Attracting funding for commercial biotechnology research and development depends, in part, on the ability to assure investors that the company has the intellectual property rights necessary to commercialize products resulting from its R&D."). Interpreting the assignment of "all rights, title and interest" to a patent to mean something less than sole ownership of the whole patent creates uncertainty and confusion, and will discourage investment in future projects, thus hampering innovation and discovery, the very lifeblood of a knowledge-based economy. "One of the fundamental purposes behind Patent and Copyright Clauses of the Constitution was to promote national uniformity in the realm of intellectual property" and thereby avoid such confusion. *Bonita Boats v. Thunder Craft Boats*, 489 U.S. 141, 162 (1989).

The Court should grant the writ, resolve the conflicts with this Court and the circuit courts, and restore certainty and uniformity to this economically vital area of law.

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STATEMENT OF THE CASE

1. IBEP's Patent Assignment

In December 1982, IBEP entered into a series of contracts with Inter-Yeda and the Government of Israel, in which IBEP agreed to invest between $7 and $10 million to fund four biotech research programs in Israel. These programs would be carried out by Inter-Yeda, with the assistance of Yeda, another Israeli research company, over a five-year term, ending on December 27, 1987. Both IBEP and Inter-Yeda agreed that the purpose of the research was to make biotech discoveries which could subsequently be commercialized. Yeda was not a party to any of the IBEP contracts.

In return for IBEP's investment, Inter-Yeda, made the following patent assignment to IBEP:[1]

> **On behalf of the Partnership** [IBEP], Developer [Inter-Yeda] **shall apply for and obtain patents** in Developer's and/or Yeda's name(s) on all inventions **resulting from the R&D Programs** . . . ; provided, however, that beneficial ownership of **all rights, title and interest in and to such patents** and patent applications that form a part of the Proprietary Information **shall be and hereby are assigned to the Partnership**. . . .

(App. 88-89 (emphasis added).)[2] The assignment was part of a contract between IBEP and Inter-Yeda called the Sub-Research and Development Agreement ("Sub-R&D Agreement"). (App. 78-98.) The Sub-R&D Agreement defined "Proprietary Information" to mean the following:

> any and all inventions, patent applications, and patents (wherever applied for or granted), trade secrets, technical information (including all blueprints, plans, workbooks, drawings, specifications,

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[1] This assignment was subject to Inter-Yeda's option to purchase the patent in exchange for royalties specified in a separate Technology, Option and Sale Agreement. As the Federal Circuit recognized, Inter-Yeda "never exercised that option." (App. 6.) Thus, the provisions of the TOS Agreement never took effect.

[2] The Sub-R&D Agreement likewise provided that "any and all of the Proprietary Information shall become the sole property of the Partnership." (App. 89 ¶ 10(A).)

> formulas and processes) and other technology or knowhow developed in the R&D programs.

(App. 81.) The Sub-R&D Agreement did not reference the possibility of fractional or joint patent ownership. In that regard, individual inventors could be named on patents obtained on behalf of IBEP, "provided that no proprietary rights are vested in such individuals." (App. 90.) Like the other agreements, the Sub-R&D Agreement is governed by Israeli law. (App. 95.)

The Private Offering Memorandum circulated to the IBEP investors in 1982, and specifically approved by Inter-Yeda, informed the investors that the work to commercialize the research results to be owned by IBEP would take much longer than the five-year project term. (App. 62; App. 64-65.) IBEP investor Newton Becker confirmed this understanding by testifying that IBEP's financing investment was intended as "seed money" to finance research and development, and that IBEP would be the sole owner of any patents and commercial products resulting from the research. (App. 71 ¶ 10.)

2. The Research

In late 1986 or early 1987, a three-member Inter-Yeda research team—David Wallach, Hartmut Engelmann, and Dan Aderka—"discovered and partially purified [TBP] in human urine." (App. 7.) TBP "proved capable of combating rheumatoid arthritis" and is the subject matter of U.S. Patent No. 5,981,701 (the " '701 patent"). (App. 8.)

In July 1987, after Wallach submitted the research results to Inter-Yeda, Inter-Yeda's CEO wrote to Wallach confirming Inter-Yeda's sole ownership of TBP. (App. 75-77.)

On September 13, 1987, and in accordance with paragraph IX(A) of the Sub-R&D Agreement, Israeli Patent Application No. 83878 (the "'878 application") was filed in Yeda's name. (App. 8.) The '878 application claimed the discovery and the partial purification of TBP. (*Id.*) The '701 patent claims priority from the '878 application.

In September 1987, a fourth inventor, Menachem Rubinstein reviewed the '878 application in his capacity as R&D Manager at Inter-Yeda. (App. 45-46.) At the time, Rubinstein was a "full time" employee of Inter-Yeda. (App. 73-74 ¶ 76; App. 9 n.4.) Rubinstein immediately "realized the commercial potential" of TBP and decided that Inter-Yeda had "to do further purification in order to exploit the commercial value of this protein." (App. 46.)

In 1988, Inter-Yeda employees Rubinstein and Engelmann worked together to further purify TBP in order to commercialize the discovery. This work was a continuation of the partial purification of TBP, which began no later than April 1987, before the expiration of the Sub-R&D Agreement. (App. 7, 9.) In fact, the lead inventor wrote that Rubinstein's contribution to the TBP invention was "marginal" because he "joined the project . . . **after** much knowledge of the TBPs had been gained already (including: . . . the bioassay by which their purification has been monitored, and detailed knowledge of how to collect, concentrate, and enrich the TBPs in various purification steps as detailed in claim 8 of the priority document [the '878 application] . . .)." (App. 53 (emphasis added).)

On September 12, 1988, Yeda filed the application that led to the '701 patent. (App. 9.) The '701 patent contains three claims. (App. 8.) Claim 1 covers TBP. Claims 2 and 3 describe the partial purification of TBP, which occurred in early 1988. Enbrel contains a form of TBP that falls within the '701 patent.

On July 11, 1988, Rubinstein and the other inventors executed a written assignment, purporting to assign their rights in the invention to Yeda. The '701 patent issued on November 9, 1999, naming Wallach, Englemann, Aderka, and Rubinstein as inventors.

3. The Litigation

IBEP filed its patent infringement lawsuit against Amgen on September 2, 2002. In 2003, Yeda intervened and filed a motion for summary judgment arguing that it, not IBEP, was the owner of the '701 patent based on the July 11, 1988 assignment. The district court granted the motion.

On appeal, in *Israel Bio-Engineering Project v. Amgen Inc.* ("*IBEP I*"), 401 F.3d 1299, the Federal Circuit reversed. The Federal Circuit agreed with IBEP that any discovery made in the R&D Programs by Inter-Yeda would pass to IBEP under the Sub-R&D Agreement assignment despite the inventors' purported assignment to Yeda. It agreed that "[u]nder Israeli law, the discoveries of an employee are the property of his or her employer." *Id.* at 1304. The court reversed summary judgment because "there were genuine issues of material fact on the issue of whether the inventors were Inter-Yeda employees" at the time of the invention, and remanded for further proceedings. (App. 10-11.)

On remand, the district court again entered summary judgment. Ignoring Israeli law, the district court ruled that Rubinstein was the "presumptive owner of the '701 patent" and that because his work on Claims 2 and 3 occurred in 1988, "those Claims do not fall within the operation of the Sub-R&D Agreement." (App. 31-32, 35.) Accordingly, IBEP had only a "partial interest" in the patent and did not have standing to sue. (App. 35.)

In the decision below, the Federal Circuit framed the issue as "discern[ing] the scope of the subject matter to which IBEP was assigned 'all rights, title and interest.'" (App. 20.) The answer is in the assignment itself: IBEP owns "all rights, title and interest" to "**patents**" covered by the assignment. (App. 88.) The '701 patent, as the Federal Circuit itself acknowledged, is such a patent. (App. 23). Accordingly, IBEP owns the whole '701 patent, not an undivided share as the Federal Circuit ruled. (*Id.*)

The Federal Circuit also acknowledged that Israeli contract law does not apply a "plain meaning" rule; an Israeli "court must consider 'not just the contract language, but all of the extrinsic evidence regarding the circumstances surrounding the contract, particularly the negotiations prior to the formation of the contract and the parties' conduct in the course of performance and afterwards.'" (App. 19.) In *State of Israel v. Aprofim Housing and Enterprise* (1995) 49(2) P.D. 265, the Supreme Court of Israel held that all of the surrounding facts related to the parties intent are material to contract interpretation and must be considered, even when the contract is unambiguous.

While paying lip service to *Aprofim*, the Federal Circuit refused to take account of much of the evidence supporting IBEP's interpretation—like the Private Offering Memorandum and Becker's testimony—even though *Aprofim* requires the fact-finder to consider all of the relevant circumstances. Instead, the Federal Circuit decided, on summary judgment, that the definition of "Proprietary Information" limited the scope of the assignment to portions of the '701 patent that were discovered before 1988—even though the assignment language does not permit co-ownership of covered patents. In doing so, the Federal Circuit took on the role of factfinder by weighing conflicting evidence and holding that IBEP's evidence was "not ultimately persuasive" and that "Yeda's interpretation is **more consistent** with the intention of the parties." (App. 20 (emphasis added).) It ultimately held that the assignment of "all rights, title and interest" to covered "patents" paradoxically resulted in shared ownership of the '701 patent.

Relying on *Ethicon, Inc. v. U.S. Surgical Corp.*, 135 F.3d 1456 (Fed. Cir. 1998), the Federal Circuit also did an about-face from its ruling in *IBEP I* and ruled that Rubinstein held an ownership interest in the '701 patent because he was a co-inventor, and could validly assign that interest to Yeda. (App. 22-23.) This also enabled the court to sidestep the settled legal effect of Inter-Yeda's "all rights, title and interest" assignment. The court declined to apply Israeli law of employer ownership and its own precedent in *IBEP I* which, contrary to the ruling below, holds that Rubinstein's invention would automatically belong to his employer Inter-Yeda and could pass to IBEP under the assignment. *IBEP I*, 401 F.3d at 1304.

This petition followed.

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REASONS FOR GRANTING THE WRIT

I. THE FEDERAL CIRCUIT'S DECISION THAT AN ASSIGNMENT OF "ALL RIGHTS, TITLE AND INTEREST" TO A U.S. PATENT RESULTS IN CO-OWNERSHIP CONFLICTS WITH THIS COURT'S PRECEDENT AND OTHER CIRCUIT COURT DECISIONS

The Federal Circuit ruled that IBEP had only shared ownership of the '701 patent, without standing to sue, under a patent assignment that conveyed "**all** rights, title and interest" to patents within its scope. Review is warranted here because that ruling cannot be squared with this Court's decision in *Waterman v. MacKenzie*, 138 U.S. 252 (1891), and subsequent circuit court authority. A direct conflict between the decision of the court of appeals of which review is being sought and a decision of the Supreme Court is one of the strongest possible grounds for securing the issuance of a writ of certiorari. *Lambert v. Wicklund*, 520 U.S. 292, 293 (1997). A conflict between the decision and other appellate decisions provides equally compelling grounds for review. *See* Sup. Ct. R. 10(a); *Braxton v. United States*, 500 U.S. 344, 347 (1991).

In the seminal *Waterman* decision, the Court held that "[t]he monopoly thus granted [by the Patent Act] is one entire thing, and cannot be divided into parts, except as authorized by those laws." 138 U.S. at 255. According to this Court, federal patent law recognizes only three forms of patent assignment. *Id.* A patentee may convey "either [1] the whole patent, . . . ; or [2] an undivided part or share of that exclusive right; or [3] the exclusive right under the patent within and throughout a specified part of the United States." *Id.* According to the Court, "[a] transfer of either of these three kinds of interests is an assignment," with a transfer of the first or third of these interests enabling the assignee to sue for infringement in its name alone. *Id.*

The Court's application of these principles to the assignment at issue in *Waterman* is particularly instructive. There, Sara Waterman, the owner of a patent for an improvement in fountain pens, had "assigned to the firm of Asa L. Shipman's Sons **all her right, title and interest** in the invention and the patent," which was later assigned to Shipman himself. *Id.* at 257-58 (emphasis added). The assignment was made in a mortgage, subject to defeasance if Waterman paid off her loan. The Court found that, despite Waterman's reversionary interest, the assignment conveyed "the whole title in the patent" to Shipman, and that Shipman "was the person, and the only person, entitled to maintain such a bill [for patent infringement] as this." *Id.* at 261. Waterman's subsequent assignment to the plaintiff had no legal effect. *Id.* at 258.

Until now, the Federal Circuit has likewise held that the assignment of "all right, title and interest" accomplishes an assignment of the "whole patent" and confers standing to sue for infringement. In *State Contracting & Eng'g Corp. v. Condotte Am., Inc.*, for example, the Court explicitly relied on *Waterman* to hold that the contract's transfer of " 'the entire right, title and interest in the inventions,' . . . constitutes an assignment" that "transferred all substantial rights to State Contracting and" conferred "standing to bring this infringement suit against the contractors." 346 F.3d 1057, 1063 (Fed. Cir. 2003) (citing *Waterman*, 138 U.S. at 255); *see also FilmTec Corp. v. Hydranautics*, 982 F.2d 1546, 1550-53 (Fed. Cir. 1992) (the assignment of "the full and entire domestic right, title and interest" in any invention conceived under an R&D

contract transferred the entire title to a patent, even though the inventor perfected the claim limitations after leaving the contractor's employ).

The Federal Circuit's decision below, however, has abandoned those settled principles by holding that the assignment of "all rights, title and interest" results in co-ownership and no standing—a result that is impossible under the *Waterman* paradigm. Although *Waterman* recognized that one could assign "an undivided share" of a patent, it made equally clear that the assignment of "all right, title and interest" accomplishes an assignment of the "whole patent" and confers standing to sue. *Id.* at 255, 257-58. Like the assignment in *Waterman*, the assignment to IBEP made no mention of the possibility of fractional ownership. Moreover, there is no record evidence here that the parties to the contract ever contemplated such an outcome; to the contrary, the evidence shows that the parties understood that product commercialization could extend well beyond the five-year research period.

The Federal Circuit's disparate analysis between this case and cases such as *State Contracting & Eng'g Corp.* underscores the conflict and confusion on the question presented. The conflict and confusion is further magnified by the Federal Circuit's exclusive jurisdiction over patent issues and the immediate nationwide scope of its ruling.

Because the Sub-R&D assignment here does not convey undivided shares of patents, but instead "all rights, title, and interest" to whatever patents are within its scope—there were only two possibilities under *Waterman*. Either (1) the assignment did not apply at all because the patent does not cover "an invention resulting from the R&D Programs," or (2) the assignment did apply to the '701 patent and effected a transfer of the "whole patent." *See Waterman*, 138 U.S. at 255.

The Federal Circuit already excluded the first possibility when it ruled that IBEP established an ownership interest in at least part of the '701 patent. (App. 23) It is law of the case that TBP was discovered within the five-year term of the Sub-R&D Agreement, and that the assignment applies to that discovery and claim 1 of the '701 patent. That left only one possibility under *Waterman*. Having found that the subject matter of claim 1 is an "invention resulting from the R&D Programs" and "form[s] a part of the Proprietary Information," the Federal Circuit had *a fortiori* determined that the assignment attaches to the '701 patent. Under *Waterman*, the undisputed fact that the '701 patent covered at least one "invention resulting from the R&D Programs" that "formed a part of the Proprietary Information" compelled a conclusion that IBEP had "the whole title in the patent." *Id.* at 261.

The language of the assignment underscores the simplicity of the transaction: investment capital in return for ownership of patents covering inventions "resulting from" or "developed in" the R&D Programs. (App. 88). TBP is indisputably such an invention. (App. 8.) Therefore, the '701 patent is indisputably covered by the assignment. The Federal Circuit has construed the patent assignment statute, 35 U.S.C. § 261, to mean that "property rights, including ownership, attach to patents as a whole, not individual claims." *Ethicon*, 135 F.3d at 1466. Contrary to both the statute and *Waterman*, however, the Federal Circuit in the decision below ruled that the assignment covered only an individual claim, not the whole patent.

Regardless of whether claims 2 and 3 were "resulting from the R&D Programs" or were "Proprietary Information"—questions of contractual intent controlled by Israeli law, as discussed below—the Federal Circuit could not, consistent with *Waterman* and the patent assignment language, find that the inclusion of these claims into the patent results in a partial assignment that deprives IBEP of its standing to sue for infringement.

Simply put, the Federal Circuit may not overrule the settled legal effect of an "all rights, title and interest" assignment, by holding that it results in co-ownership—a result that neither of the contracting parties ever intended, and that conflicts with well-settled Supreme Court precedent.

II. THE FEDERAL CIRCUIT'S DECISION CONFLICTS WITH MORE THAN FIFTY YEARS OF CIRCUIT COURT PRECEDENT ESTABLISHING THAT STATE LAW GOVERNS WHETHER AN EMPLOYER OWNS AN EMPLOYEE INVENTION

The Court also should grant review because the Federal Circuit's decision conflicts with circuit court precedent holding that state law controls whether an employer owns the inventions of his employees. *See* Sup. Ct. R. 10(c); *Teets v. Chromalloy Gas Turbine Corp.*, 83 F.3d 403 (Fed. Cir. 1996) (relying on Florida law to find that employer automatically owned employee's invention under implied contract); *Jamesbuy Corp. v. Worcester Value Co.*, 443 F.2d 205 (1st Cir. 1971) (dispute over employer's ownership of patent developed by employee would be decided by Massachusetts law); *E. F. Drew & Co. v. Reinhard*, 170 F.2d 679, 682 (2d Cir. 1948) (L. Hand, J.)

("it is uniformly held that an employee . . . may promise that he will assign all inventions which he may make, and the courts of New York, as well as those of other jurisdictions, enforce such contracts specifically.")

Here, for the first time, the Federal Circuit created an irrebuttable federal presumption of employee ownership to find that Rubinstein held an ownership interest in the '701 patent and validly assigned that interest to Yeda. The Federal Circuit disregarded Israeli law, which dictates that Inter-Yeda would automatically own any patents developed by Rubinstein, which it could then validly assign to IBEP.

In *IBEP I*, the Federal Circuit properly reversed summary judgment because there was evidence that the inventors were employed by Inter-Yeda, which made the assignment to IBEP, and "[u]nder Israeli law, the discoveries of an employee are the property of his or her employer." 401 F.3d at 1304.

In the decision below, however, the Federal Circuit disregarded its own prior holding in these proceedings. The Federal Circuit's about-face in the same case on such an important issue, without so much as a comment, underscores the confusion created by the Federal Circuit's decision and the need for review.

The decision below cannot be reconciled with *IBEP I* or any of the other authority applying state law to determine employer ownership of employee inventions. The Federal Circuit held that "Rubinstein was a presumptive co-owner of the patent because he was listed as one of four inventors on the face of the patent," without regard to the contrary provision of Israeli law.

To reach this conclusion, the Federal Circuit improperly extended the holding of *Ethicon, Inc. v. U.S. Surgical Corp.* to nullify more than fifty years of precedent establishing that the issue of employer ownership of inventions is governed by state law. *Ethicon* did not involve an employer/employee relationship. The *Ethicon* Court ruled that a research assistant, who was not an employee and was not even paid for his work, was a joint owner of the patent at issue. 135 F.3d 1456, 1459. Nonetheless, in the decision below, the Federal Circuit, relying on *Ethicon*, created an irrebuttable federal presumption of employee ownership and thus ignored the rulings of the First and Second Circuits, and its own prior rulings, that state law controls the ownership of inventions made in the course of employment. Because the Federal Circuit has fashioned a new rule that is contrary to settled circuit court precedent, plenary review is necessary.

This conflict takes on added magnitude because the Federal Circuit's exclusive jurisdiction over the interpretation and application of the patent laws gives the ruling below a national scope that effectively preempts conflicting decisions of other federal courts.

The Court should grant review to resolve the conflict between the decision below—which decided an employee's ownership rights as a matter of federal law—and the numerous circuit court decisions holding that such issues should be decided as a matter of state law.

III. THE FEDERAL CIRCUIT'S DECISION CONFLICTS WITH THIS COURT'S PRECEDENT ESTABLISHING THAT DISPUTED EVIDENCE OF CONTRACTUAL INTENT CANNOT BE RESOLVED ON SUMMARY JUDGMENT

The Court should also grant certiorari in this case for the straightforward reason that the Federal Circuit's decision cannot be reconciled with this Court's decisions on the proper role of the judiciary on summary judgment. Contrary to this Court's precedents, the Federal Circuit failed to give proper effect to the controlling Israeli contract law that makes all surrounding facts material to contract interpretation. The Federal Circuit improperly resolved disputed inferences and weighed the evidence to decide contested issues of contractual intent.

Under Rule 56, a court may grant summary judgment "if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law." In 1986, this Court issued three critical decisions on the proper use of summary judgment. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242 (1986); *Celotex Corp. v. Catrett*, 477 U.S. 317 (1986); *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574 (1986).

These decisions and the Court's subsequent precedents carefully circumscribed the lower courts' role on summary judgment: courts are required to look to the governing substantive law to determine which facts are material and may not weigh the evidence or determine the truth of the matter but only determine whether there is a genuine issue for trial. In *Anderson*, the Court held that "the substantive law will identify which facts are material" for purposes of summary judgment. 477 U.S. at 248. And, the Court explained, "disputes over facts that might affect the outcome of the suit under the governing law will properly preclude the entry of summary judgment." *Id.* ("[I]t is the substantive law's identification of which facts are critical and which facts are irrelevant that governs").

Anderson also made clear that Rule 56 "by no means authorizes trial on affidavits." *Anderson*, 477 U.S. at 255. Rather, "[c]redibility determinations, the weighing of the evidence, and the drawing of legitimate inferences from the facts are jury functions, not those of a judge. . . . " *Id.* "The evidence of the nonmovant is to be believed, and all justifiable inferences are to be drawn in his favor." *Id.* *Accord Hunt v. Cromartie*, 526 U.S. 541, 552 (1999); *Matsushita*, 475 U.S. at 587. Summary judgment is unwarranted "[i]f reasonable minds could differ as to the import of the evidence. . . ." *Anderson*, 477 U.S. at 250-51. The decision below conflicts with these commands in two distinct ways.

First, the decision conflicts with the Court's ruling that the governing substantive law—here Israeli contract law—determines which facts are material for purposes of summary judgment and that factual disputes that might affect the outcome under Israeli law properly preclude summary judgment. *See* 477 U.S. at 248. All surrounding facts are material to the interpretation of a contract under Israeli law. Because all surrounding facts must be considered, contract interpretation under Israeli law is an inherently factual inquiry, ill-suited to summary judgment.

Under *Anderson*, any dispute over contractual intent in light of all of those surrounding circumstances should have "properly preclude[d] the entry of summary judgment." 477 U.S. at 248. Indeed, summary judgment is generally inappropriate in contract cases where evidence of intent and other extrinsic circumstances must be considered. *E.g.*, *Fanucchi & Limi Farms v. United Agri Prods.*, 414 F.3d 1075, 1082 (9th Cir. 2005) ("Determining the parties' intent is a highly fact-specific inquiry. Such inquiries are not generally suitable for disposition on summary judgment.").

The Federal Circuit, however, conspicuously declined to even consider extrinsic evidence supporting IBEP's interpretation of the assignment, such as the Private Offering Memorandum or Becker's testimony. IBEP's evidence established that IBEP intended to own "all rights, title and interest" to patents on inventions resulting from the R&D Programs, such as patents covering the commercialization of discoveries developed in those programs, including the purification of TBP. Under the contract and the evidence, IBEP did not agree to forfeit sole ownership if commercialization extended, as expected, beyond the Sub-R&D research period. Accordingly, IBEP's evidence should have properly precluded summary judgment. Having failed to recognize the proper role of Israeli contract law, the Federal Circuit's summary judgment analysis conflicts with the binding pronouncements of this Court.

Second, the Federal Circuit's finding that IBEP's evidence was "not ultimately persuasive" and that "Yeda's interpretation is more consistent with the intention of the parties" sanctioned the very sort of trial by affidavit this Court's summary judgment precedents forbid. Yeda, of course, was not even a party to the assignment, and

Inter-Yeda submitted no evidence on the issue of contractual intent.

The Federal Circuit refused to give IBEP the benefit of justifiable inferences that could be drawn in its favor. *See Anderson*, 477 U.S. at 255. It acknowledged that claim 1 of the '701 patent was invented in the R&D Programs. (App. 8.) The court admitted that the purification process that led to claims 2 and 3 was ongoing in the R&D Programs, only to be completed a few months later. (App. 9.) Based on those facts alone, a reasonable jury could conclude that, under the terms of the patent assignment, (1) the '701 patent covers "an invention resulting from the R&D Programs," and (2) the '701 patent "forms a part of the Proprietary Information" because it covered an invention "developed in" the R&D Programs. Instead, the Federal Circuit gave Yeda the benefit of the opposite inference.

Review is also an appropriate exercise of the Court's supervisory power over the federal judiciary to ensure that the limitations on the lower courts' "gatekeeper" role are not eroded by the increasingly expansive application of Rule 56. *See* Sup. Ct. R. 10(a). No question of federal civil procedure is more important than whether a litigant is entitled to a jury trial on the merits; it is ultimately a question of constitutional dimension. *See, e.g.*, *Adickes v. S. H. Kress & Co.*, 398 U.S. 144 (1970) ("The right to confront, cross-examine and impeach adverse witnesses is one of the most fundamental rights sought to be preserved by the Seventh Amendment provision for jury trials in civil cases. The advantages of trial before a live jury with live witnesses, and all the possibilities of considering the human factors, should not be eliminated by substituting trial by affidavit and the sterile bareness of summary judgment.").

Because this case is a conspicuous example of the trend of lower court decisions that have strayed from the mandates of the Court's summary judgment precedents, an exercise of the Court's supervisory power is warranted here.

IV. THE CONFLICT WITH THE SUPREME COURT AND CIRCUIT COURTS CONCERNS A MATTER OF OVERRIDING IMPORTANCE AS TO WHICH NATIONAL UNIFORMITY IS REQUIRED

"One of the fundamental purposes behind the Patent and Copyright Clauses of the Constitution was to promote national uniformity in the realm of intellectual property." *Bonita Boats*, 489 U.S. at 162. The conflict between the Federal Circuit's decision and the precedents of this Court and the circuit courts seriously impedes such uniformity, thus having a chilling effect on the willingness of investors and businesses to enter into development agreements. One of the key elements in the creation of the biotechnology industry was the presence of venture capital. Ed Penhoet, *The Biotechnology Industry From Birth to Adolescence,* Report of Bay Area Science and Innovation Consortium, p. 7 (June 2004). Venture capital continues to be an important source of sustenance for the industry, amounting to $2.8 billion in 2003 alone. G. Stephen Burrill, *The Shape of Things to Come*, Report of Bay Area Science and Innovation Consortium, p. 60. (June 2004) But patent issues and access to capital threaten further advancement in the industry. *Id.* ("Nearly all of the biotech companies surveyed [in 2003 by the U.S. Department of Commerce] cited regulation, patent issues and access to capital among the top barriers to advancement.")

With uncertainty surrounding the meaning of such simple phrases as "all rights, title and interest," important sources of capital will refrain from funding risky research and development projects for fear that their straightforward bargains (investment money in return for whole patent ownership) will be rewritten to produce a result that neither party intended.

For similar reasons, the Court should also review the Federal Circuit's creation of an irrebuttable federal presumption of employee ownership, a ruling that departs from decades of circuit court precedent.

This lack of uniformity is especially intolerable in light of the undeniable importance of the questions presented. Research and development is increasingly financed by investment vehicles that bargain for ownership or royalties in exchange for their investment. The risks posed by such an investment are substantial. IBEP and other R&D investors are not simply buying existing patents to license and enforce; their investment supports the research itself which often yields no patentable inventions or commercial success. Yet such investment fuels the engine of innovation, and investors and research companies must have certainty and stability in order to undertake their commercial arrangements. *See, e.g.*, Gary H. Moore, *Joint Ventures and Strategic Alliances: Ownership of Developed Intellectual Property—Issues and Approaches*, 893 PLI/Pat 187 (2007).

The success of these arrangements, indeed the future of the R&D financing industry, depends on commercial certainty in the application of patent assignments—especially those that were obviously written to accomplish a transfer of the "whole patent" and the corresponding right of unilateral enforcement. The Court should grant review to foster that certainty and stave off the type of unsettling results—such as co-ownership and unenforceability—endorsed by the decision below.

Given the critical role that jury trials play in the justice system, it is not surprising that the rise in summary judgments and the corresponding decline in jury trials has been the subject of extensive scholarly commentary. Marc Galanter, *The Hundred Year Decline of Trials and the Thirty Years War*, 57 Stan. L. Rev. 1255, 1258-59 (2005) ("In 2003, only 1.7% of civil terminations occurred during or after trial."); Patricia M. Wald, *Summary Judgment at Sixty*, 76 Tex. L. Rev. 1897 (1998). The near extinction of the federal jury trial is often attributed to the widespread use of summary judgment since the Supreme Court trilogy—often going beyond the limits on summary judgment that those decisions carefully preserved. *See, e.g.,* Martin H. Redish, *Summary Judgment and the Vanishing Trial: Implications of the Litigation Matrix*, 57 Stan. L. Rev. 1329, 1330 (2005) ("Changes in the law of summary judgment quite probably explain at least a part of the dramatic reduction in federal trials."); Arthur R. Miller, *The Pretrial Rush to Judgment: Are the "Litigation Explosion," "Liability Crisis" and Efficiency Clichés Eroding Our Day in Court and Jury Trial Commitments?*, 78 N.Y.U. L. Rev. 982, 1064 (2003) (survey showed that recent federal decisions from circuits throughout the country that "appear to have encroached on the factfinder's role in deciding Rule 56 motions.").

Review of this case is warranted because the Federal Circuit has far exceeded its gatekeeping role. The Federal

Circuit impermissibly weighed the evidence and resolved a dispute regarding what the parties to the contract intended the assignment to cover by finding that IBEP's evidence was "unpersuasive." This case presents the Court with an opportunity to reverse a trend that threatens a pillar of our judicial system.

◆

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted,

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May 18, 2007.

United States Court of Appeals for the Federal Circuit

06-1218

ISRAEL BIO-ENGINEERING PROJECT,

Plaintiff-Appellant,

v.

AMGEN INC., IMMUNEX CORPORATION,
WYETH, and WYETH PHARMACEUTICALS, INC.,

Defendants-Appellees,

and

YEDA RESEARCH AND DEVELOPMENT CO., LTD.,

Defendant-Appellee,

and

INTER-LAB LTD. and SERONO INTERNATIONAL S.A.,

Defendants-Appellees.

Thomas L. Hamlin, Robins, Kaplan, Miller & Ciresi L.L.P., of Minneapolis, Minnesota, argued for plaintiff-appellant Israel Bio-Engineering Project. With him on the brief were Stephen P. Safranski, Brian A. Mayer, and Ross A. Abbey.

Barbara R. Rudolph, Finnegan, Henderson, Farabow, Garrett & Dunner, L.L.P, of Washington, D.C., argued for defendants-appellees Amgen Inc., et al. With her on the brief were Gerald F. Ivey and William L. Strauss. Of counsel on the brief were Stuart L. Watt, Monique L. Cordray, Karen L. Nicastro, Kathleen Fowler, and Gail Katz, Amgen Inc., of Thousand Oaks, California; Vicki G. Norton, Wilson Sonsini Goodrich & Rosati, P.C., of San Diego, California; and Nicole W. Stafford, Wilson Sonsini Goodrich & Rosati, P.C., of Austin, Texas.

Nicholas Groombridge, Weil, Gotshal & Manges LLP, of New York, New York argued for defendant-appellee Yeda Research and Development Co., Ltd. With him on the brief were Michael Eisenberg, Daniel J. Melman, and Peter Sandel. Of counsel was John D. Garretson, Fish & Richardson, P.C. of New York, New York.

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Appealed from: United States District Court for the Central District of California Judge R. Gary Klausner

DECIDED: January 29, 2007

Before BRYSON, PROST, Circuit Judges, and SARIS, District Judge.*

SARIS, District Judge.

This appeal involves a complex dispute over the ownership of a patent. Plaintiff-Appellant Israel Bio-Engineering Project ("IBEP") appeals from a judgment in a patent infringement action granting Defendant-Appellee Yeda Research and Development Company, Ltd.'s ("Yeda") motion for summary judgment on the ground that IBEP lacked standing to bring the suit because it did not have sole ownership of the patent. This court affirms.

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* Honorable Patti B. Saris, District Judge, United States District Court for the District of Massachusetts, sitting by designation.

FACTUAL BACKGROUND

1. Four Contracts

This dispute over ownership of the patent involves four inter-related contracts. Yeda is an Israeli corporation that markets and commercializes inventions resulting from research conducted at the Weizmann Institute of Science, a multi-disciplinary research institute. Yeda entered into negotiations with Inter-Yeda Ltd., a joint venture formed in Israel in 1979 between Yeda and Inter-Pharm, an Israeli company wholly owned by Serono International S.A., to finance various Weizmann research projects and to commercialize the results of the research. On September 14, 1981, Yeda and Inter-Yeda executed a handwritten agreement, which provided that Inter-Yeda would finance four specified research projects during a five year project term, including the one at issue here. This initial agreement was later amended, as will be explained later. That same day, Yeda sent a side letter to Inter-Yeda offering to cooperate with Inter-Yeda in revising the contract if it found outside funding.

Shortly afterwards in 1982, Inter-Yeda began negotiating with IBEP, a New York limited partnership, to secure funding for the four research projects. These negotiations generated three agreements. First, on December 27, 1982, IBEP entered into a contract with the State of Israel ("the R&D Contract") whereby IBEP committed to spend between $7 million and $10 million on four research programs. Paragraph 5 of the R&D Contract provides: "[IBEP] will be entitled, [subject to two paragraphs which are not applicable], to exploit all the Research results, including any Patents, in any manner, including the manufacture of Products, granting of licenses, transfer and/or sale of any rights in any matter resulting from the Research." The Israeli government consented to the terms of the two contracts which IBEP and Inter-Yeda were about to enter. Three days later, IBEP signed a pair of contracts with Inter-Yeda on December 30, 1982. All three contracts were set to expire on December 27, 1987, and were to be construed in accordance with the laws of the State of Israel.[1]

The first contract between IBEP and Inter-Yeda, called the Sub-Research and Development Contract ("Sub-R&D Contract"), provided that IBEP would fund the research operations conducted by Inter-Yeda in cooperation with Yeda. Of particular significance to this dispute, Paragraph IX(A) of this contract specified:

> On behalf of the Partnership [IBEP], Developer [Inter-Yeda] shall apply for and obtain patents in Developer's and/or Yeda's name(s) on all inventions *resulting from the R&D Programs* which Developer, in its sole discretion, considers advisable to apply for and obtain; provided, however, *that the beneficial ownership of all rights, title and interest in and to such patents and patent applications that form a part of the Proprietary Information* shall be and hereby are assigned to the Partnership from the date the Partnership shall have made the first payment to the Developer pursuant to this Agreement in perpetuity, unless and until the Developer shall have purchased the Proprietary Information in respect thereof according to the provisions of the TOS Agreement.

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[1] Portions of one of the three agreements – the so-called TOS Agreement – were set to expire well beyond 1987. However, these sections are largely irrelevant.

(Emphasis added). Paragraph X(A), entitled "Property Rights," then provides:

> Subject to the provisions of the TOS Agreement, any and all of the Proprietary Information shall become the sole property of the Partnership [IBEP]. Subject to the provisions of Paragraph IX above regarding the registration of patents in Developer's [Inter-Yeda's] and/or Yeda's name(s), Developer shall assign to [IBEP] all its rights, title and interest in and to the Proprietary Information and shall require all persons employed by it, presently or in the future, to do the same unless and until Developer shall become the owner of all of the Partnership's rights, title and interest in and to the Proprietary Information in accordance with the TOS Agreement. Nothing contained herein shall prevent Developer from including in any patent registration the name(s) of the individual inventor(s) as required by law, provided that no proprietary rights are vested in such individuals.

For purposes of this contractual provision, the term "Proprietary Information" was defined, in relevant part, to mean:

> any and all inventions, patent applications and patents (wherever applied for or granted), trade secrets, technical information (including all blueprints, plans, workbooks, drawings, specifications, formulas and processes) and other technology or knowhow *developed in the R&D programs.*

(Emphasis added). The R&D Programs referenced by this agreement were designed to "be effective for a period coterminous with . . . the Execution Period defined in the

R&D Agreement" with Israel, that is until December 27, 1987.

The other contract between IBEP and Inter-Yeda is the Technology Option and Sale Agreement ("The TOS Contract"), which was executed on December 30, 1982. In the paragraph entitled "Property Rights," the contract repeats, "Any and all of the Proprietary Information developed *during the term of the Sub-R&D Agreement* shall become the sole property of the Partnership [IBEP] subject to the right of Inter-Yeda to exercise the Option with respect thereto, as provided in paragraph 5 hereof." (Emphasis added). In Paragraph 5, entitled "Options to Purchase Proprietary Information," the TOS Contract granted Inter-Yeda the sole and exclusive option to "purchase all of [IBEP's] rights, title and interest in and to the Proprietary Information relating to each Product that has been Reduced to Practice or in respect to which a patent application has been filed prior to the expiration or termination of the Sub-R&D Agreement [December 27, 1987]." If Inter-Yeda timely exercised the option, it had to make certain payments to IBEP. Inter-Yeda never exercised that option.

Moreover, the TOS agreement expressly discusses research and development after the term of the Sub-R&D Contract. It gives IBEP the right to finance additional research and development if, after the term of the Sub-R&D agreement and during the term of the TOS Contract, Inter-Yeda "desires to conduct further research and development with respect to the Proprietary Information."[2] It then provides: "If after the termination of the Sub-R&D Agreement and during the term hereof, any Product is Reduced to Practice or if a patent application is filed with respect thereto, [IBEP] shall be entitled to payments. . . . " IBEP's right to royalties would be proportionately reduced if "more money is spent to conduct additional research and development . . . than has been spent by [IBEP]."

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[2] There is no evidence that the provisions of this paragraph were triggered.

Finally, one day after IBEP and Inter-Yeda signed these contracts, Inter-Yeda and Yeda amended their original 1981 hand-scrawled agreements. This amended agreement distinguishes between "unrelated results," "pre-existing results," "new results," and "any other results." It provides: "The title in and to any New Result which will be discovered or developed during the Project Term other than an Unrelated Result shall belong to [IBEP] immediately upon its discovery or development." The parties agreed that title to any "pre-existing results" stemming from Yeda's research between September 14, 1981 and December 30, 1982 would still vest in Yeda. Moreover, it provides that title to "any other results which shall not belong to [IBEP]" would belong to Yeda. The "project term" of the 1981 contract was defined to be the five-year period of the contract effective September 14, 1981.

2. The Inventions

By April 1987 – after the expiration of the original 1981 contract, but prior to the termination of the 1982 contracts – three scientists, who worked in the R&D program directed at identifying novel anti-cellular factors, discovered and partially purified the Tumor Necrosis Factor Binding Protein ("TBP") in human urine. This protein, when bound to a substance in the body called the Tumor Necrosis Factor ("TNF"), proved capable of combating rheumatoid arthritis. TBP is the subject matter of U.S. Patent No. 5,981,701 (the "'701 patent") entitled "Tumor Necrosis Factor Inhibitory Protein and its Purification," which issued on November 9, 1999, naming four inventors: David Wallach, Hartmut Engelmann, Daniel Aderka, and Menachem Rubinstein. Yeda was named the assignee of the patent. The '701 patent contains three separate claims. '701 Patent col. 16 ll.34-65. Claim 1 recites: "A protein capable of inhibiting the binding of TNF to cells and of inhibiting the cytotoxic effect of TNF, wherein said protein is obtainable from human urine" and has certain features. *Id.* col. 16 ll.34-36. The parties do not dispute that this subject matter was discovered prior to the expiration of the Sub-R&D Agreement.[3] On September 13, 1987, Yeda filed the Israeli patent application, No. 83878 (the "'878 priority document"), relating to these discoveries.

Claims 2 and 3 of the '701 Patent, however, relate to inventions made in 1988, after the termination of IBEP's Sub-R&D Contract with Inter-Yeda. Claim 2 covers "[a] substantially purified protein obtainable from human urine, capable of interacting with TNF so as to inhibit the binding of TNF to cells and to inhibit the cytotoxic effect of TNF" and containing a specifically identified amino acid sequence. *Id.* col.16 ll.51-55. Claim 3 recites "[a] pharmaceutical composition for use in treating conditions where TNF . . . is to be eliminated from the body or its effect in the body is to be antagonized, comprising a protein in accordance with claim 2 and a pharmaceutically acceptable carrier." *Id.* col.16 ll.60-65.

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[3] While the record is not clear on this point, there still appears to be a dispute as to whether the invention took place in 1986 or 1987. This issue is not material to this appeal.

One of the named inventors, Dr. Menachem Rubinstein,[4] began working with the other inventors on this project in January 1988, *after* the expiration of the Sub-R&D Contract. Both parties agree that Rubinstein was brought into the research team at this time to help purify and sequence the protein listed in claims 2 and 3 of the '701 patent. He worked with Dr. Engelmann in 1988 "to complete the purification," in Rubinstein's words, and they purified it sufficiently to determine an amino acid sequence. The inventors were able to isolate and purify this protein and ascertain the amino acid sequence of this protein sometime during 1988. Rubinstein and the other inventors executed an agreement dated July 11, 1988, assigning their rights in the invention to Yeda.[5] The patent application was not filed until September 12, 1988; it claimed priority based on the '878 priority document filed in September 1987.

It is undisputed that Professor Rubinstein's special skills, in collaboration with Dr. Engelmann, resulted in the substantially purified TBP discussed in claims 2 and 3 of the '701 patent and in the patent application. Purification of the protein was needed to allow the scientists to determine the amino acid sequence. IBEP claims that one of the named inventors, David Wallach, partially purified the protein in 1987, although the record seems to support (at best) a finding that Wallach's "studies" were focused on purifying the protein and he was "attempting to do so." Indeed, the record demonstrates that in 1988, experiments to purify and characterize TBP were ongoing. Nevertheless, IBEP downplays Rubinstein's contribution as a continuation of Wallach's partial purification.

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[4] There is evidence that Rubenstein was the R&D manager of Inter-Yeda. Rubinstein was employed by both Weizmann and Inter-Yeda at the time of the invention. He worked four days a week for Inter-Yeda. The parties still seem to dispute his employment status, and we do not wade into that dispute here.

[5] "Under Israeli law, the discoveries of an employee are the property of his or her employer." *Israeli Bio-Eng'g Project v. Amgen, Inc.*, 401 F.3d 1299, 1304 (Fed. Cir. 2005).

3. Litigation

In 2002, IBEP filed an action in the United States District Court for the Central District of California, alleging that the defendant pharmaceutical companies Amgen, Inc., Immunex Corporation, Wyeth, and Wyeth Pharmaceuticals, Inc. (collectively "Amgen") infringed claim 1 of the '701 patent with the pharmaceutical Enbrel®, a genetically engineered protein used to treat severe rheumatoid arthritis and psoriasis. Shortly after the filing of the suit, Yeda and Serono moved to intervene; only Yeda prevailed. In 2003, Yeda filed a motion for summary judgment against IBEP, arguing that IBEP could not claim full title to the '701 patent because the inventors were not rightly considered Inter-Yeda employees at the time of the agreement and thus did not pass the invention by operation of Israeli law to Inter-Yeda, which was contractually required to assign title to IBEP. Agreeing with this argument, the district court granted the motion for summary judgment. IBEP appealed.[6] We reversed, holding there were genuine issues of material fact on the issue of whether the inventors were Inter-Yeda employees at the time of the invention under Israel law. Of significance to this appeal, this court held:

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[6] The original appeal involved other issues not relevant here.

> On remand, if IBEP is able to establish that Wallach was an employee of Inter-Yeda at the time of the invention, IBEP may be able to establish that it has an ownership interest in the patent. IBEP can establish an ownership interest in the patent as long as the rights of even one of the inventors has passed to it. Even an ownership interest, however, would not be sufficient to give IBEP prudential standing to sue for infringement, as IBEP would have to join all the other co-owners in order to establish such standing.

Israel Bio-Eng'g Project v. Amgen Inc., 401 F.3d 1299, 1304-05 (Fed. Cir. 2005)[7] (citations omitted). We noted: "The district court did not reach the question of standing." *Id.* at 1305 n.4.

After the case was remanded to the district court, Yeda again moved for summary judgment, this time (not surprisingly) with a focus on standing. Yeda argued that IBEP lacked standing because the Sub-R&D Contract expired in 1987 and because claims 2 and 3 of the '701 patent were based on post-1987 discoveries outside of the project term. As such, total ownership of the entire patent could not have been passed to IBEP under the Sub-R&D Contract. At most, Yeda contended, IBEP could claim only a pro rata undivided share of the entire patent, and without full ownership of the '701 patent, IBEP lacked standing to sue.

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[7] In the previous appeal, this court allowed Serono and Inter-Lab, Ltd. to intervene. *IBEP*, 401 F.3d at 1307. These parties have joined in Yeda's brief.

In a well-reasoned opinion, the district court allowed the defendant's motion for summary judgment, holding that IBEP lacked standing because claims 2 and 3 of the '701 patent "did not fall within the operation of the sub-R&D agreement," and even if IBEP had an ownership interest in TBP, the subject matter in claim 1, IBEP "at most" had a partial interest in the whole patent. *Israel Bio-Eng'g Project v. Amgen Inc.,* No. CV 02-06860 RGK (MANx) (C.D. Cal. Dec. 21, 2005). Stymied again, IBEP filed a timely notice of appeal. This court has appellate jurisdiction under 28 U.S.C. § 1295.

DISCUSSION

1. Standard of Review

Whether a party has standing to sue is a question of law that this court reviews *de novo. Prima Tek II, L.L.C. v. A-Roo Co.,* 222 F.3d 1372, 1376 (Fed. Cir. 2000). If Appellant did not have standing to maintain an infringement action, then jurisdiction is not proper on appeal. *See id.*

Although there are multiple ways to dispose of challenges to standing in the district court, the parties here addressed standing through a motion for summary judgment, one frequently used method. *See generally* 13A Charles Alan Wright, Arthur R. Miller & Edward H. Cooper, *Federal Practice and Procedure* § 3531.15 (2d ed. 1984) (pointing out that "[m]any cases have suggested that summary judgment procedure is appropriate," but arguing it is "better to use the preliminary hearing device as a means of requiring the plaintiff to carry the burden of establishing standing"). This court reviews a district court's grant of summary judgment *de novo. Conroy v. Reebok Int'l, Ltd.,* 14 F.3d 1570, 1575 (Fed. Cir. 1994). Summary judgment is appropriate when there is no genuine issue as to any material fact and the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(c); *Johnston v. IVAC Corp.,* 885 F.2d 1574, 1576-77 (Fed. Cir. 1989). In deciding whether summary judgment was appropriate, we view the evidence in a light most favorable to the party opposing the motion and with doubts resolved in favor of the opponent, which in this case is IBEP. *See Transmatic, Inc. v. Gulton Indus., Inc.,* 53 F.3d 1270, 1274 (Fed. Cir. 1995).

2. Ownership

The key question on appeal is whether IBEP had standing to maintain the patent infringement action against Amgen without the joinder of Yeda, the assignee of the patent. IBEP argues that it has standing because it is the sole exclusive owner of the patent by virtue of the Sub-R&D agreement.

It is a bedrock tenet of patent law that "an invention presumptively belongs to its creator." *Teets v. Chromalloy Gas Turbine Corp.,* 83 F.3d 403, 406 (Fed. Cir. 1996). Consistent with the presumption that the inventor owns his invention, the "[p]atent issuance creates a presumption that the named inventors are the true and only inventors." *Ethicon, Inc. v. U.S. Surgical Corp.,* 135 F.3d 1456, 1460 (Fed. Cir. 1998). When, as here, multiple inventors are listed on the face of the patent, each co-owner "presumptively owns a pro rata undivided interest in the entire patent, no matter what their respective contributions." *Id.*

This holding that "a joint inventor as to even one claim enjoys a presumption of ownership in the entire patent" flows from the language of 35 U.S.C. § 116, which permits joint inventors to "apply for [a] patent jointly" even though: "(1) they did not physically work together or at the same time, (2) each did not make the same type or amount of contribution, or (3) each did not make a contribution to the subject matter of every claim of the patent."

Still, issues of patent ownership are distinct from questions of inventorship. *See Beech Aircraft Corp. v. EDO Corp.,* 990 F.2d 1237, 1248 (Fed. Cir. 1993) ("It is elementary that inventorship and ownership are separate issues."); *see also Jones v. Hardy,* 727 F.2d 1524, 1528 (Fed. Cir. 1984) ("each claim must be considered as defining a separate invention."). We have held: "All that is required of a joint inventor is that he or she (1) contribute in some significant manner to the conception or reduction to practice of the invention, (2) make a contribution to the claimed invention that is not insignificant in quality, when that contribution is measured against the dimension of the full invention, and (3) do more than merely explain to the real inventors well-known concepts and/or the current state of the art." *Pannu v. Iolab Corp.,* 155 F.3d 1344, 1351 (Fed. Cir. 1998) (citations omitted).

This interplay between inventorship and ownership creates the anomalous situation that a co-inventor of even a single claim can then assert a right of joint ownership over an entire patent with multiple claims. *See Fina Oil & Chem. Co. v. Ewen,* 123 F.3d 1466, 1473 (Fed. Cir. 1997) (citations omitted) ("One need not alone conceive of the entire invention, for this would obviate the concept of joint inventorship."); *see also Ethicon*, 135 F.3d at 1460 ("This rule presents the prospect that a co-inventor of only one claim might gain entitlement to ownership of a patent with dozens of claims.").

Thus, under the rule in *Ethicon,* a co-inventor of even one claim in the '701 patent, which has three claims, presumptively has a pro rata undivided ownership interest in the entire patent. For this reason, the district court held that IBEP had no standing to press its patent infringement action because Menachem Rubinstein was a co-inventor of the subject matter of claims 2 and 3, which was not discovered until after the conclusion of the R&D program, and therefore, IBEP did not have sole ownership of the patent.

3. Standing

IBEP contends that it had standing because under the terms of the Sub-R&D Contract it had the right to the assignment of title to all patents "resulting from" the R&D program. Standing to sue for infringement stems from the Patent Act, which provides: "[a] patentee shall have remedy by civil action for infringement of his patent." 35 U.S.C. § 281. As defined in § 100(d), "patentee" includes not only the patentee to whom the patent was issued but also "the successors in title to the patentee." 35 U.S.C. § 100(d).

Patent owners may assign or transfer their ownership interests in the patent as personal property. 35 U.S.C. § 261.[8] Under long established law, a patentee or his assignee may grant and convey to another: (1) the whole patent, (2) an undivided part or share of that exclusive right, or (3) the exclusive right under the patent within and throughout a specified part of the United States. *See Vaupel Textile KG v. Maccanica Euro Italia, S.A.A.*, 944 F.2d 870, 873 (Fed. Cir. 1991); *see also Waterman v. Mackenzie,* 138 U.S. 252, 255 (1891) (holding that in the first and third cases, the assignee may sue in its name alone; in the second case, it may sue "jointly with the assignor"). Where one co-owner possesses an undivided part of the entire patent, that joint owner must join all the other co-owners to establish standing. *IBEP,* 401 F.3d at 1305 (citing *Prima Tek II,* 222 F.3d at 1377). With certain exceptions not applicable here, one co-owner has the right to limit the other co-owner's ability to sue infringers by refusing to join voluntarily in the patent infringement suit. *Ethicon,* 135 F.3d at 1468 (holding "as a matter of substantive patent law, all co-owners must ordinarily consent to join as plaintiffs in an infringement suit"); *see also Schering Corp. v. Roussel-UCLAF SA,* 104 F.3d 341, 345 (Fed. Cir. 1997) ("One co-owner has the right to impede the other co-owner's ability to sue infringers by refusing to voluntarily join in such a suit."). Absent the voluntary joinder of all co-owners of a patent, a co-owner acting alone will lack standing. *Prima Tek II,* 222 F.3d at 1377 (recognizing that the general rule that "a patentee should be joined, either voluntarily or involuntarily, in any infringement suit brought by an exclusive licensee" was "prudential rather than constitutional in nature.").

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[8] Section 261 states that "patents shall have the attributes of personal property. Applications for patent, patents, or any interest therein, shall be assignable in law by an instrument of writing."

IBEP claims it has standing to sue for patent infringement because it owns the whole patent by assignment. *See Speedplay, Inc. v. Bebop, Inc.,* 211 F.3d 1245, 1250 (Fed. Cir. 2000); *Rite-Hite Corp. v. Kelley Co., Inc.,* 56

F.3d 1538, 1551 (Fed. Cir. 1995) (en banc). To prevail, IBEP must establish that Inter-Yeda was contractually required to assign all Rubinstein's ownership rights in the '701 patent to it. Ownership depends upon "the substance of what was granted" through assignment. *Vaupel Textile,* 944 F.2d at 874. In construing the substance of the assignment, a court must carefully consider the intention of the parties and the language of the grant. *Id.*

4. The Scope of the Assignment

To elude the steel trap of the *Ethicon* joint ownership rule, IBEP argues that the Sub-R&D Contract, read properly under applicable Israeli law, gives IBEP exclusive ownership over the patent because this agreement gives it the right to an assignment of "all rights, title and interest" to "all inventions *resulting from* the R&D Programs." IBEP contends that a genuine issue of material fact remains on the issue of whether Rubinstein's further purification of the protein described in claims 2 and 3 "resulted from" the R&D Program.

As a threshold matter, Yeda contends that this argument, as well as others, was waived because it was not presented in the district court and was raised for the first time on appeal. *See Pentax Corp. v. Robison,* 135 F.3d 760, 762 (Fed. Cir. 1998) (citations omitted) (stating that "this court will not address issues raised for the first time on appeal or issues not presented on appeal"). IBEP concedes – as it must – that it did not make this exact argument in support of ownership. Plaintiff argues that it is not making a new claim of ownership, but rather a new argument to support its persistent claim of ownership under the Sub-R&D Contract. *See Lebron v. Nat'l R.R. Passenger*

Corp., 513 U.S. 374, 379 (1995) (citations omitted) (holding that "[o]nce a federal claim is properly presented, a party can make any argument in support of that claim; parties are not limited to the precise arguments they made below").

Ordinarily, this court has declined to consider arguments that were not presented to the district court. *See, e.g., Pandrol U.S.A., L.P. v. Airboss Ry. Prods., Inc.,* 320 F.3d 1354, 1366-67 (Fed. Cir. 2003) (holding that defendant's arguments were waived when they were not raised in response to the motion for summary judgment). "With a few notable exceptions, such as some jurisdictional matters, appellate courts do not consider a party's new theories, lodged first on appeal." *Sage Prods., Inc. v. Devon Indus., Inc.* 126 F.3d 1420, 1426 (Fed. Cir. 1997) (declining to consider new infringement arguments on appeal). This rule serves the salutary purpose of permitting the trial judge most familiar with a complex record to address the issue first. Thus, any party who fails to raise an argument in the trial court does so at his peril.

This case, however, is in the gray area. IBEP based its original argument before the district court on the language of Paragraph IX of Sub-R&D Contract, albeit not the "resulting from" language also contained in that section. Because the parties argued about the meaning of this paragraph in the district court, we conclude they are not bound by the precise arguments raised below.

IBEP protests bitterly that it has never seen the fruits of its investments, and that any contract construction that gave it a non-exclusive ownership in an invention developed during the R&D period would defeat the intention of the parties in violation of Israeli contract law. According to

IBEP's expert, under Israeli contract law, the meaning of a contract depends exclusively on the intention of the parties. (Decl. of Gabriela Shalev ¶ 22.) To determine the purpose of the contract, a court must consider "not just the contract language, but all of the extrinsic evidence regarding the circumstances surrounding the contract, particularly the negotiations prior to the formation of the contract and the parties' conduct in the course of performance and afterwards." *See State of Israel v. Aprofim Hous. & Enter.*, 49(2) P.D. 265 at 40, ¶ 17 (1995) ("A contract is interpreted on the basis of the parties' intent. This intent constitutes the goals, aims, interests, and plan that the parties wished jointly to implement.").

The question, then, is whether the parties intended only to assign to IBEP title to patents for Proprietary Information developed during the R&D period, which ended in December 1987, or whether they intended to give IBEP the right to the assignment of all patents, patent applications, or inventions resulting from the R&D programs. Yeda highlights the language in the Sub-R&D Contract that provides that "the beneficial ownership of all rights, title, and interest in and to such patents and patent applications that *form a part of the Proprietary Information* shall be and hereby are assigned to [IBEP]." (Emphasis added). The term "Proprietary Information" is in turn defined by the contract as patents, patent applications, and inventions "developed in the R&D programs." IBEP's interpretation is rooted in the first clause of the sentence of this paragraph which provides that on behalf of IBEP, Inter-Yeda "shall apply for and obtain patents" in its name and/or Yeda's name, "on all inventions *resulting from the R&D Program* which [Inter-Yeda], in its sole discretion, considers advisable to apply for and obtain."

(Emphasis added). Put another way, IBEP's argument requires this court to discern the scope of the subject matter to which IBEP was assigned "all rights, title and interest."

IBEP's reliance on the "resulting from" language is not ultimately persuasive because that provision, when read as a whole, expressly limits IBEP's property rights by providing that IBEP should only receive "beneficial ownership of all rights, title and interest" in the Proprietary Information formed during the R&D program. By definition, the R&D program was of finite duration; thus, the period during which the Proprietary Information could be discovered is time-limited. IBEP argues that the R&D Agreement between IBEP and Israel lends support to its interpretation because it gives IBEP an entitlement to exploit and commercialize "rights in any matter resulting from the Research." However, this document cannot be so broadly read because it also explicitly approves the time limitations incorporated in the Sub-R&D Contract by expressly referencing this agreement.

Moreover, Yeda's interpretation is more consistent with the intention of the parties as illustrated by the other contracts. According to IBEP's expert on Israeli law, "the interpretive rule of the contract as a whole relates not only to an isolated contract but also to a set of documents or agreements made between the same parties, as a reliable source in realizing the purpose of the contract." (Decl. of Gabriela Shalev ¶ 24.) The TOS Contract includes language that similarly limits property rights to Proprietary Information "developed in the R&D programs," which means "developed *during* the term of the Sub-R&D Agreement." (Emphasis added). This wording confirms the limited temporal scope of the Sub-R&D Contract's Proprietary

Information term. By definition, when the R&D program ended in December 1987, IBEP was not entitled to further assignments of any other newly developed inventions, even when these inventions built on proprietary information developed during the R&D process. In the TOS agreement, the parties negotiated with exquisite detail IBEP's financial rights with respect to such subsequent research. While it may rue the bargain it struck, IBEP is bound by it.

Alternatively, IBEP protests that by combining the three claims in one patent, Inter-Yeda forfeited its rights to claims 2 and 3. However, under the Sub-R&D Contract, Inter-Yeda could file for patents in its discretion; it had the option under the Sub-R&D Contract to aggregate claims invented during the R&D programs together with claims for inventions developed afterwards in the same patent, even though the effect of this decision was to deprive IBEP of exclusive ownership over the whole patent. Thus, even though there is some evidence to support IBEP's factual argument that Rubinstein's substantial purification of TBP was a continuation of work started by Wallach in the R&D program, IBEP has not claimed that the subject matter of claims 2 and 3 was discovered during that time period. Significantly, IBEP has not challenged inventorship, nor has it brought a breach of contract claim.

IBEP cites the well-established rule that patent assignments "attach to patents as a whole, not individual claims." *Ethicon,* 135 F.3d at 1466. While this is true, the Sub-R&D Contract governs IBEP's property rights, and it is entitled only to ownership of patents on the subject matter included within Proprietary Information, nothing more. As such, while an assignment of a patent must attach to the patent as a whole, here the issue was ownership of a future invention, which became the subject matter of only one claim.

In a final twist on its argument, IBEP argues that Rubinstein's assignment of the '701 patent to Yeda was a nullity because the patent assignment in the Sub-R&D Contract is a present assignment of future rights. *FilmTec Corp. v. Allied-Signal Inc.,* 939 F.2d 1568, 1572 (Fed. Cir. 1991) ("If an assignment of rights in an invention is made prior to the existence of the invention, this may be viewed as an assignment of an expectant interest."). Under IBEP's theory, once the inventions in claims 2 and 3 were made and the patent application filed, legal title automatically flowed to it as the assignee, and the assignor-inventor Rubinstein had nothing left to assign to Yeda. *Id.* It argues that this interpretation is consistent with the provision in the Sub-R&D Contract that "no proprietary rights" are vested in the named inventors. Again, this strained interpretation assumes incorrectly that IBEP had an "expectant interest" in Rubinstein's post-project term invention. This interpretation is inconsistent with the language of the contract and intention of the parties to preclude vesting of proprietary rights in the named inventors with respect to Proprietary Information, as defined.[9]

To sum up, Rubinstein was a presumptive co-owner of the patent because he was listed as one of four inventors on the face of the patent. It is undisputed that after the R&D program ended, Rubinstein, beginning in January 1988, discovered the substantially purified protein and the specific amino acid sequence described in claims 2 and 3 of the '701 patent. Rubinstein then assigned his ownership rights to Yeda. Rubinstein was not required to assign his ownership share to IBEP under the Sub-R&D Contract, and Yeda properly became a co-owner of the patent by virtue of claims 2 and 3. Even assuming IBEP has co-ownership of the patent under the Sub-R&D Contract because claim 1 was discovered in 1987, the district court properly ruled that IBEP has at most a pro rata undivided ownership interest in the '701 patent pursuant to the Sub-R&D Contract's assignment clause. Rubinstein's assignee, Yeda, also owns at least a pro rata undivided ownership interest in the whole '701 patent and throughout the two appeals has made it quite clear that it wants no part of the litigation. Without a complete ownership interest or the voluntary joinder of Yeda, IBEP lacks standing to sue for infringement.

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[9] Moreover, as this argument was not raised below, it is waived. *See Pandrol U.S.A.*, 320 F.3d at 1366-67.

CONCLUSION

The Judgment of the United States District Court for the Central District of California is affirmed.

AFFIRMED

P-SEND, ENTER, JS-6

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

CIVIL MINUTES – GENERAL

Case No. CV 02-6860-RGK (MANx) Date: December 21, 2005

Title: ***ISRAEL BIO-ENGINEERING PROJECT v. AMGEN, INC., et al.***

Present: The Honorable R. GARY KLAUSNER, U.S. DISTRICT JUDGE

Sharon L. Williams	Not Reported	N/A
Deputy Clerk	Court Reporter/Recorder	Tape No.

Attorneys Present for Plaintiffs:	Attorneys Present for Defendants:
Not Present	Not Present

Proceedings: **(IN CHAMBERS)**

(1) Intervenors/Counterclaimants Inter-Lab, Ltd. and Serono International S.A.'s Motion for Summary Judgment (DE 269);

(2) Amgen, Inc., Immunex Corp., Wyeth, and Wyeth Pharmaceuticals, Inc's Motion for Summary Judgment of Non-Infringement (DE322); and

(3) Intervenor, Defendant, Intervenor, Counterclaimant Yeda Research's Motion for Summary Judgment (DE 327)

I. INTRODUCTION

Israel Bio-engineering Project, ("IBEP") brought suit against Defendants Amgen, Inc., Immunex Corporation, Wyeth and Wyeth Pharmaceuticals, Inc. (collectively "Defendants") for infringement of U.S. Patent No. 5,981,701 ("'701 Patent). Yeda Research and Development Company Ltd. ("Yeda") and Inter-Lab Ltd. and Serono International ("Serono") filed motions to intervene. The Court granted Yeda's motion and denied Serono's motion. Subsequently, Yeda, an Israeli firm that markets and commercializes new developments from research at the Weizmann Institute of Science in Israel ("Weizmann"), intervened seeking a declaration that it, not IBEP, owns the '701 patent.

On December 16, 2003, Yeda filed a Motion for Summary Judgment against IBEP on the ground that IBEP cannot claim title to the '701 Patent. Defendants filed a Joinder in Yeda's Motion. The Court ruled that IBEP failed to establish patent ownership. Specifically, the Court struck IBEP's "single transaction" contract theory, which would have extended to December 1987 the applicable project term, and therefore, the period in which IBEP could take title to the patent. The Court also ruled against IBEP as to the theory that its contractual relationship with Inter-Yeda, and the researchers' employment by Inter-Yeda gave IBEP title to the patent. (February 18, 2004 Order re Yeda's Motion for Summary Judgment ("February 18 Order").) On March 31, 2004, this Court entered judgment in favor of: (1) Defendants on all counts of IBEP Complaint; (2) Yeda on its Counterclaim against

IBEP; and (3) Defendants as to their first counterclaim against IBEP.[1] (March 30, 2004 Judgment.)

Two appeals were made to the Federal Circuit. One was made by Serono as to this Court's denial of its Motion to Intervene. The other was made by IBEP to challenge the grant of summary judgment. On March 15, 2005, the Federal Circuit decided that this Court erroneously denied Serono's request to intervene as defendants in this case and reversed the decision. The Federal Circuit also decided that this Court correctly decided summary judgment on the "single transaction" contract theory, but erroneously granted summary judgment as to the employer-employee theory. As to the latter theory of patent ownership, the Federal Circuit found the evidence either raised, or potentially raised, a genuine issue of material fact as to whether IBEP owned the patent based on the inventors' employment status. Accordingly, the case has been remanded for redetermination of this issue.

By approval of this Court, Yeda has filed the current Motion for Summary Judgment on the ground that IBEP does not have standing to bring this lawsuit because it lacks sole ownership of the '701 Patent. Serono, who has since intervened in this action, joins in Yeda's motion.

II. FACTUAL BACKGROUND

On September 14, 1981, Yeda entered into a five-year agreement ("1981 Contract") with Inter-Yeda Ltd., an Israeli joint venture formed in 1979 between Yeda and

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[1] As to their second counterclaim against IBEP, the Court declared the claim moot, and dismissed the claim without prejudice.

Inter-Pharm (an Israeli company, wholly owned by Serono International S.A.), for Inter-Yeda to finance the various Weizmann research projects and commercialize the results of such research. Under its terms, title to all results discovered or developed during the project term, which ended on September 14, 1986, was to vest in Yeda. On the same date, Yeda sent a letter to Inter-Yeda offered to cooperate with Inter-Yeda in revising the 1981 Contract if an outside funding source was located.

In 1982, Inter-Yeda entered into negotiations with IBEP so Inter-Yeda could fulfill its financial commitments to Yeda through IBEP funding. The negotiations resulted in three contracts. One of the contracts, the Research and Development Agreement ("R&D Agreement"), was executed by IBEP and the State of Israel on December 27, 1982. Under the R&D Agreement, IBEP agreed to expend between $7 and $10 million in four research programs within the Execution Period, which is defined as a 60-month (or five year) period from the date the agreement was executed. The other two agreement, the Sub-Research and Development Agreement ("Sub-R&D Agreement"), and the Technology Option and Sale Agreement ("TOS Agreement") were both executed by IBEP and Inter-Yeda on December 30, 1982. Under the Sub-R&D Agreement, Inter-Yeda agreed to carry out IBEP's research obligations under the R&D Agreement in exchange for IBEP funding. Additionally, IBEP would receive title to any discovery arising from such research during the effective period of the contract, which expired on December 27, 1987. The TOS Agreement granted Inter-Yeda an option to purchase the rights, title and interest to the discoveries owned by IBEP as a result of the research performed under the Sub R&D Agreement.

On December 31, 1982, Yeda and Inter-Yeda amended the 1981 Contract to address certain issues related to the IBEP funding. One such issue was the ownership rights to discoveries made during the contract period. According to the amendments, title to all results related to the research, which were discovered during the 1981 Contract term, and after December 30, 1982 (i.e., the date of the Sub R&D Agreement), were to vest in IBEP. All other results, including results discovered during the 1981 Contract term and before December 30, 1982, were to vest in Yeda.

In April 1987, after expiration of the 1981 contract but before the end of the Sub-R&D Agreement and TOS Agreement term, researchers affiliated with Yeda and Inter-Yeda discovered the Tumor Necrosis Factor Binding Protein ("TBP"). TBP later proved useful in treating rheumatoid arthritis by binding to another protein, Tumor Necrosis Factor ("TNF"), and preventing or mitigating RNF's potentially deleterious effects. According to IBEP, that discovery was made as a result of one of the Weitzmann projects founded by IBEP. The April 1987 discovery formed the basis of the '701 Patent, entitled "Tumor Necrosis Factor Inhibitory Protein and its Purification." The patent lists David Wallach ("Wallach"), Hartmut Engelmann, Daniel Aderka and Mencham Rubinstein ("Rubinstein") as inventors, and Yeda as the assignee.

In the February 18 Order, this Court found, and the Federal Circuit agree, that IBEP had no ownership interest the 1987 discovery pursuant to the 1981 Contract, because the 1981 Contract expired on September 14, 1986. The Court also found, and the Federal Court also agreed, that under Israeli law, title to any discovery made in 1987 within the scope of the Sub-R&D Agreement would pass to

Inter-Yeda by operation of law, then to IBEP by contract, if the discovery was made by Inter-Yeda employees. However, this Court found that the researchers were not Inter-Yeda employees at the time the discovery was made. Contrary to this Court's findings, the Federal Circuit ruled that there are genuine issues of material fact as to whether Wallach was an Inter-Yeda employee at the time the 1987 discovery was made. The Federal Circuit further ruled that, even if Wallach was an Inter-Yeda employee, IBEP would not have standing to sue for infringement unless IBEP could establish that the remaining three inventors' interests also passed to IBEP by virtue of their employment relationship with Inter-Yeda. As to employment relationship of the remaining three inventors, the Federal Circuit found that this Court failed to adequately conduct an analysis on this issue, and remanded the case for further review. In light of the Federal Circuit's Mandate, this Court allowed further discovery on the employment issue.

In essence, Yeda argues in its current Motion for Summary Judgment that, based on current evidence, the issue of whether the four inventors were Inter-Yeda employees in 1987 is irrelevant. Yeda's reasoning is based on its position that the '701 Patent consists of both 1987 and post-1987 inventions. Because the Sub-R&D Agreement expired in December 1987, ownership derived from the post-1987 discoveries could not have passed to IBEP under that contract. Since no assignments were made to IBEP, and IBEP can, at best, claim only partial interest in the patent, it does not have proper standing to sue for infringement.

II. JUDICIAL STANDARD

Under the Federal Rules of Civil Procedure, summary judgment is proper only where "the pleadings, depositions, answers to interrogatories, and admissions on file, together with affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." Fed. R. Civ. P. 56(c). Upon such a showing, the Court may grant summary judgment "upon all or any part thereof." Fed. R. Civ. P. 56(a), (b).

To prevail on a summary judgment motion, the moving party must show there are no triable issues of fact as to matters upon which it has the burden of proof at trial. *See Celotex Corp. v. Catrett*, 477 U.S. 317, 325 (1986). On issues where the moving party does not have the burden of proof at trial, the moving party is required only to show that there is an absence of evidence to support the nonmoving party's case. *See Celotex Corp. v. Catrett*, 477 U.S. at 326.

To defeat a summary judgment, the non-moving party may not merely rely on its pleadings or on conclusory statements. Fed. R. Civ. P. 56(e). Nor may the non-moving party merely attack or discredit the moving party's evidence. *National Union Fire Ins. Co. v. Argonaut Ins. Co.*, 701 F.2d 95, 97 (9th Cir. 1983). The non-moving party must affirmatively present specific admissible evidence sufficient to create a genuine issue of material fact for trial. *See Celotex Corp. v. Catrett*, 477 U.S. at 324.

III. DISCUSSION

Yeda argues that the portion of the '701 Patent attributable to Rubinstein's invention (i.e., Claims 2 and 3) was not discovered until 1988, after the expiration of the Sub-R&D Agreement. As such, Rubinstein's interest in the patent could not have immediately transferred to IBEP by virtue of that agreement, even if Rubinstein was an Inter-Yeda employee. Consequently, when the '701 Patent was issued, IBEP, at most, had only partial ownership of the patent. Since no later assignments were ever made to IBEP giving it complete ownership of the patent, it lacks standing to sue for infringement. For the following reasons, this Court agrees.

A. Rubinstein Had Proper Ownership Interest in the '701 Patent When the Patent was Issued

It is well-established that the named inventor of a patent is the presumptive owner of that patent. *Ethicon, Inc. v. United States Surgical Corp.,* 135 F.3d 1456, 1460 (Fed. Cir. 1998). In the context of joint inventorship, each co-inventor presumptively owns a pro rata undivided interest in the entire patent, regardless of their respective contributions. *Id.* at 1465. The inventors may transfer their ownership interests by written assignment because federal law provides that patents have the attributes of personal property. 35 U.S.C. § 261. In fact, the inventors may even have a legal duty to effectuate such a transfer by virtue of a contractual or other obligation. *Id.*

The parties agree that Rubinstein is listed as an inventor on the face of the '701 Patent. (IBEP's Statement of Genuine Issues in Opposition to Yeda's Motion for Summary Judgment ("IBEP's Statement of Genuine

Issues"). No. 7.) Therefore, it is presumed that Rubenstein had legitimate ownership interest in the patent at the time of its issuance, and that, in the absence of preemptive contractual or other obligation, he made a legitimate assignment of his interest to Yeda.

It has already been established that the Sub-R&D Agreement expired on December 30, 1987. Furthermore, it is undisputed that Rubinstein's work on the '701 Patent did not occur until 1988, after the contract terms of the Sub-R&D Agreement expired. (IBEP's Statement of Genuine Issues, No. 30.) Therefore, unlike its position regarding the other inventors, IBEP does not argue that it acquired Rubinstein's interest because he was an employee of Inter-Yeda. Rather, IBEP appears to challenge Rubinstein's status as a joint inventor, and therefor, as a joint owner of the patent at the time he made the assignment to Yeda. (IBEP's Opp'n, pp. 12-13.) As stated by the Federal Circuit, the inventors, as named in an issued patent, are presumed to be correct. *Hess v. Advanced Cardiovascular Systems, Inc.*, 106 F.3d 976, 980 (Fed. Cir. 1997). Therefore, any party challenging this presumption must show by clear and convincing evidence that a misjoinder of inventors occurred. *Id.* As discussed below, IBEP has failed to meet this heavy burden.

First, IBEP has introduced evidence showing that Yeda previously maintained that the invention of the '701 Patent was made in April 1987 (as opposed to 1988). (Tietjen Decl., Exh. 29, p.i, Exh. 30, p. 4; Chou Decl., Exh. 8, p. 24.) However, the record shows that prior to the Federal Circuit's remand of this action, the focus of the parties' dispute and discovery was Claim 1, which Yeda concedes was discovered in 1987. Moreover, based on Yeda's argument that the relevant project term ended in

1986, the key dispute was whether the invention was discovered prior to the end of 1986, or after 1986. (*See* First Amended Complaint, ¶ 64; Tietjen Decl., Ex. 30, p. 13, lines 11-16.) In the face of Yeda's current argument, its pre-remand argument regarding the invention date(s) was, at most, incomplete, but certainly not inconsistent or contradictory to its former position. Therefore, IBEP's evidence in support of this argument is unavailing and fails to create a triable issue of material fact as to the issue of inventorship.

IBEP further argues that, according to newly discovered evidence, Wallach discovered TBP on his own in 1986; before the Yeda Agreement[2] expired. (Tietjen Decl., Exhs. 31 and 32.) Moreover, IBEP contends that Wallach had already partially purified TBP prior to Rubinstein's involvement, and that Rubinsten's work was merely "further purification" of TBP. (Tietjen Decl., Exh. 32.) Again, IBEP's evidence is unconvincing.

As held by the Federal Circuit, each patent claim qualifies as a separate invention. *Amgen v. Genetics Institute, Inc.*, 98 F.3d 1328, 1332 (Fed. Cir. 1997). An invention requires conception and reduction to practice, and the date of conception and reduction to practice can vary for different claims in the same patent. 35 U.S.C. § 102(g); *Ethicon*, 135 F.3d at 1459. "The conceived invention must include every feature of the subject matter claimed in the patent." *Id.* at 1460. However, to qualify as a joint inventor, one need only perform part of the task that produces the invention. *Id.*

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[2] The Yeda Agreement, which was addressed in the February 18 Order, provided that any "new results" discovered prior to December 31, 1986 (i.e., the contract expiration date) were covered by provisions allowing patent ownership by IBEP.

Even if IBEP can establish that the 1987 discovery was really discovered by Wallach in 1986, the subject matter of Wallach's invention covers only Claim 1 of the patent. Claims 2 and 3 of the '701 Patent describe a purified protein containing a *specific* amino acid sequence,[3] as opposed to a generalized purified protein (Melman Decl., ¶ 5, Exh. C, p. 53.) IBEP has not introduced any evidence showing that Wallach discovered the exact purified protein described in Claims 2 and 3. In fact, it is undisputed that, in January 1988, Rubinstein began working with Engelmann to achieve substantial purification of TBP, and succeeded in doing so by early September 1988. (IBEP's Statement of Genuine Issues, Nos. 10 and 11.) The '701 Patent application was not filed until September 12, 1988. (IBEP's Statement of Genuine Issues, No. 13.) Such evidence indicates that any prior purification accomplished by Wallach needed further work to achieve the ultimately derived sequence, as described by Claims 2 and 3 of the '701 Patent. The fact that Rubinstein is listed as a co-inventor of the patent simply reinforces his role as a legitimate contributor to the invention as described in those claims.

In applying the pertinent law, Claims 1, 2 and 3 all qualify as separate inventions. Based on the evidence, Rubinstein clearly performed at least part of the task that produced the specific amino acid sequence described in

---

[3] The amino acid sequence specified by the patent is: Asp-Ser-Val-Cys-Pro-Gln-Gly-Lys-Try-Ile-His-Pro-Gln-X-Asn-Ser (wherein X is an unidentified amino acid residue). (Melman Decl., ¶ 5, Exh. C, p. 53.)

Claims 2 and 3. Whether Claim 1 was discovered in 1987 or 1986 has absolutely no bearing on Claims 2 and 3, which add the specific amino acid sequence as a further limitation. Therefore, IBEP fails to introduce evidence creating a genuine dispute as to this issue, and fails to rebut the presumption that Rubinstein was correctly listed as a co-inventor of the '701 Patent.

B. Rubinstein's Ownership in the Patent did not Automatically Transfer to IBEP under the Sub-R&D Agreement

An inventor's interest in a patent may be transferred by written assignment or other legal obligation or operation of law. 35 U.S.C. § 261. As previously established, the Sub-R&D Agreement expired on December 30, 1987. Since Rubinstein's involvement in the work began in January 1988, Claims 2 and 3 of the '701 Patent could not have been invented until after that date, and those Claims did not fall within the operation of the Sub-R&D Agreement. Therefore, regardless of Rubinstein's employment status, IBEP could not have received ownership of Rubinstein's interest in the '701 Patent. Since, at most, IBEP can own only partial interest in the patent, it lacks prudential standing to sue for infringement.

IV. EVIDENTIARY OBJECTIONS

To the extent this Court's decision relies on evidence objected to by the parties, those objections are overruled.

V. CONCLUSION

Based on the foregoing, the Court **grants** Yeda's Motion for Summary Judgment and Serono's Joinder in that motion. Defendants' Motion for Summary Judgment of Non-Infringement and Serono's Motion for Summary Judgment is **denied as moot**.

IT IS SO ORDERED.

Initials of Preparer /s/ slw

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

2006-1218

ISRAEL BIO-ENGINEERING PROJECT,

Plaintiff-Appellant,

v.

AMGEN INC., IMMUNEX CORPORATION,
WYETH, and WYETH PHARMACEUTICALS, INC.

Defendants-Appellees,

and

YEDA RESEARCH AND DEVELOPMENT CO., LTD.,

Defendant-Appellee,

and

INTER-LAB LTD. and
SERONO INTERNATIONAL S.A.,

Defendants-Appellees.

NOTE: This order is nonprecedential

ORDER

(Filed Feb. 23, 2007)

Before Bryson, Circuit Judge, Prost, Circuit Judge, and Saris, District Court Judge.

A petition for rehearing having been filed by the Appellant,

UPON CONSIDERATION THEREOF, it is

ORDERED that the petition for rehearing be, and the same hereby is, DENIED.

The mandate of the court will issue on March 2, 2007.

FOR THE COURT,

/s/ Jan Horbaly
Jan Horbaly
Clerk

Dated: 02/23/2007

cc: Thomas L. Hamlin
Gerald F. Ivey, Nicholas Groombridge
Wayne M. Barsky

ISRAEL BIO-ENGINEERING V AMGEN, 2006-1218
(DCT-02-CV-6860)

EXHIBIT 24

In The Matter Of:

Israel Bio-Engineering Project v.
Amgen, Inc., et al.

Menachem Rubinstein
Vol. 1, September 24, 2005
Confidential

STIREWALT & ASSOCIATES
P.O. Box 18188
Minneapolis, MN U.S.A. 55418
(800) 553-1953

Original File RUBINS~1.TXT, 121 Pages
Min-U-Script® File ID: 2591045918

Word Index included with this Min-U-Script®

* * *

[12] Q. Was there anyone else involved?

A. His supervisor, Professor Wallach, was also involved, naturally.

Q. And what facility did you recommend that they go to?

A. The Weizmann Institute has a core facility that does routine HPLC, and that facility was intended for people who want to do routine work on HPLC of proteins and stuff like that. So Dr. Engelmann used this lab, but that wasn't a very successful attempt.

Q. And you were not involved in that attempt; correct?

A. Not directly. I – I offered advice, but not – not actual work, no.

Q. Okay. Now when you first spoke with Dr. Engelmann, did you recommend to him that he simply go to this facility to use their routine HPLC?

A. Once again, it's – there are many years went by, but –

I cannot give you precise details, but either it was common knowledge or I pointed out that in fact that there is a core facility at the Weizmann Institute for these kind of activities, so I – I cannot tell you now if it was – if I pointed out to him or he found out by himself that such a core [13] facility existed.

(Discussion off the stenographic record.)

Q. All right. So you cannot recall as you sit here today whether you recommended that he go to the core facility or whether he did that on his own; is that right?

A. That's right. I cannot –

Q. All right.

A. – tell you now.

Q. Let me show you what has been marked as Exhibit 119. Exhibit 119 is the 83878 Israeli application. Do you see that?

A. Yes.

Q. And do you see on the upper left-hand corner the filing date of September 13th, 1987? Do you see that?

A. Yes.

Q. Now as I understand it, Dr. Engelmann worked at your lab on purification in 1988 after the filing of Exhibit 119; right?

A. That's right.

Q. Can you explain to me what involvement you had with Dr. Engelmann in 1988 while he was working in your lab on purification of the protein?

MR. GROOMBRIDGE: Objection.

[14] Or let me ask you this: Could you read that question back to me, please, Mr. Reporter?

(Record read by the court reporter.)

MR. GROOMBRIDGE: Now I heard Mr. Hamlin say proteins, plural, so let's clarify the question if we could.

[14] MR. HAMLIN: The question –

Do you understand? Do you understand the question? The question is fine as read.

MR. GROOMBRIDGE: Okay. Then I withdraw my objection.

A. Okay. So you are asking me what was the – my involvement? My involvement was to teach Hartmut Engelmann how to use the technology of HPLC in the best possible way in order to isolate TBP.

Q. Okay.

A. And the principle – I told him the principles. We ran together the various chromatographic steps and attempts that we did. We decided on the choice – or actually I gave him the information on what column he should use, very impotently the correct order of the – this tandem process. We went over the data, we looked at the results, we interpreted together the results so I could explain to him and he would learn how to do [15] these things. And in this way we proceeded until the project of isolation of TBP – TBP-I was completed.

Q. And this teaching of Dr. Engelmann of the technology of HPLC took place in 1988 in your laboratory; right?

A. Yes.

Q. And this was the first time that you had suggested to Dr. Engelmann a specific purification procedure for purifying the TBP; is that right?

A. I cannot exclude the possibility that I did give him some advice before 1988 on his independent attempts to purify TBP. However, the work together that was done in my lab took place during 1988.

Q. All right. Do you have any memory of giving him specific advice on purification or any other topic related to TBP prior to 1988?

A. No, sir.

Q. When was the first time that you saw Exhibit 119, the 878 patent application?

A. In August of 1987 I was appointed as an R&D manager and chief scientist of InterPharm Laboratories. In that capacity – which was a part-time job; I didn't leave my position as an institute professor, Weizmann Institute professor, I did two jobs at the same time part time – but in my [16] capacity as R&D manager I saw the patent application after it was filed.

Q. You saw the patent application after it was filed.

A. Yes.

Q. And that was the first time that you saw it; correct?

A. I do not remember seeing it beforehand.

Q. Okay. So you don't remember seeing it before the date of filing, September 13th, 1987; is that right?

A. That's right.

Q. So you didn't have any hand in drafting the patent application prior to filing; right?

A. No, I did – I was not involved in drafting or writing or doing anything regarding this patent application.

Q. And you were not involved in any of the experiments that are described in the patent application, Exhibit 119; right?

MR. BARSKY: Objection, overbroad.

(Discussion off the stenographic record.)

MR. GROOMBRIDGE: I'll object to the form.

Q. Here – Well let me – let me ask it this way. Let [17] me ask it this way. Once you saw the patent application, did you then approach Dr. Engelmann?

A. As I answered to a previous answer, I do not remember who approached whom. All I can say, that reading this patent application it was clear to me that what needs to be done, and as a result this was – whatever I thought that should be done was – was done. Whether I initiated it or Hartmut or together we met and discussed it I cannot tell you at this point in time.

Q. And did you believe what needed to be done was further purification?

A. What needed to be done is purification of TBP to such degree of purity that will allow to determine its protein sequence.

Q. When you say "protein sequence," do you mean amino acid sequence?

A. That's right, amino acid sequence, N-terminal amino acid sequence.

Q. N as in –

A. N as in – N as in N.

Q. N as in no.

A. N as in no.

Q. Okay. Professor, is it standard practice that – that once a protein is discovered, that you [18] proceed to the purification step?

MR. GROOMBRIDGE: Objection.

MR. BAJEFSKY: Objection, vague.

A. Can you explain what do you mean by "standard practice?"

Q. Well once a protein is – is discovered, what is the next step in terms of identifying the protein?

MR. GROOMBRIDGE: Objection.

MR. BAJEFSKY: Objection.

A. It really depends on the person who is doing the research and his aims in life and science, so many things could be done once a protein is discovered. There's no standard operating procedure that will tell you I've done A and then I will do B and C and D and so on. So there's no – no rule set in stone on how to do research.

Q. And I'm – I'm sorry. I'm sorry. I didn't mean to interrupt.

A. Okay.

Q. Are – are you finished?

A. I am finished.

Q. Why is it that you thought that, after reading the patent application, purification should be the next step?

[19] A. Because I realized the commercial potential of this protein.

We are talking about 1987, '88. Molecular biology and genetic engineering are well advanced. It is clear that in order to get the best out of this invention one has to do a recombinant form of this protein, and the shortest path – not the only one, the shortest path in that case to reach a recombinant protein is to determine the sequence of this protein, and in order to determine the sequence of this protein in 1987, '88, the best way was to purify it to high degree of purity in order to be able to determine the N-terminal sequence.

Q. Was it the commercial potential of the protein that caused you, then, to believe that purification and then sequencing were the next steps?

MR. GROOMSBRIDGE: Objection.

A. In my capacity as R&D manager of InterPharm I certainly that that one has to – to do further purification in order to exploit the commercial value of this protein.

Q. And when you say that it had commercial potential, what do you mean?

A. I mean the ability to develop it into a pharmaceutical product.

[20] Q. And would the pharmaceutical product, in your view in – in 1987, 1988, be used to treat disease?

A. A pharmaceutical product normally is being used to treat diseases.

Q. And what diseases did you think that this particular protein would be useful in treating?

A. Well any disease where there is an increased level of TNF.

Q. And can you give me a couple of examples of those diseases?

MR. GROOMBRIDGE: Objection to the form, vague as to time.

MR. HAMLIN: Yeah, let me – let me – I think that's a good objection. Let – let me rephrase the question.

Q. When you determined that this protein had commercial potential, what diseases did you think that the protein would be useful in treating?

A. Well the first disease that I thought about was sepsis.

Q. And just give me a brief explanation of what sepsis is.

A. Sepsis is a systemic infection of the body with bacteria, which at that time of my studies indicated [21] that about sixty to eighty people – eighty thousand persons are – are dying of sepsis in the western world annually.

Q. Did you also consider rheumatoid arthritis as a possible disease that would be treated by this protein?

A. I do not remember.

Q. Were there any other diseases besides sepsis that you had in mind at the time?

A. I do not recall.

Q. Okay. So basically what you were thinking was that diseases caused by TNF could be treated by this – this substance; correct?

A. Certain diseases where there is an excess TNF in the body could be treated by this substance.

Q. Sir, let me direct you now to Yeda Exhibit 2, which is a copy of the '701 patent.

(Discussion off the stenographic record)

BY MR. HAMLIN:

Q. Sir, I'm showing you what has been marked as Yeda Exhibit 2, which is a copy of the '701 patent. Do you see that?

A. Yeda Deposition Exhibit 2, deposition exhibit.

Q. And that's a copy of the '701 patent; [22] correct?

A. Go through it to make sure that it's a complete copy.

Q. Sure.

A. Yes, it is. It seems to be a complete copy of that patent.

Q. Were you involved in the drafting of the patent application or the patent?

A. I was involved –

MR. BARSKY: Objection, vague.

MR. HAMLIN: You can go ahead and answer.

A. I was involved in the preparation of the – in the experiments that – that led to the drafting of the patent application. I do not recall writing anything, but it's not impossible. Certainly the drawings – some of the drawings are very familiar to me and represent my – my style in drawing such graphs, which goes many years back.

Q. Did you actually meet with the lawyers who drafted the patent?

MR. BARSKY: Tom, can you –

Are you talking about the U.S. application?

MR. HAMLIN: Yes, I'm talking about the application – the United States application for the '701 patent which was filed on September 12th, 1988.

[23] MR. GROOMBRIDGE: And –

Q. My question –

MR. GROOMBRIDGE: – let me just state –

MR. HAMLIN: Yes.

MR. GROOMBRIDGE: – the question is whether you met with the lawyers, –

MR. HAMLIN: Right.

MR. GROOMSBRIDGE: – which you're free to answer, but please don't disclose any discussions you may have had with the lawyers.

THE WITNESS: All right.

MR. HAMLIN: Well let – let me just rephrase it.

THE WITNESS: Okay.

Q. Did you meet with the U.S. lawyers?

A. Okay.

Q. Okay.

A. I understand that.

Q. All right.

A. Well I know Roger Browdy in person. We met on a number of times. I do not recall whether I did or did not meet with Roger regarding this particular patent application.

Q. Okay. Let me direct you now to column seven and to line 53. And I want to direct you specifically

*   *   *

EXHIBIT 34

[LOGO]
Department of Biological
Chemistry

Weizman Institute of Science
Rehovot 76100, Israel

Professor David Wallach
Tel: 972-8-934 3941 (or – 934 2789)
Fax: 972-8-934-3165
(or – 934-4112 or – 946-8256)
E-mail: LVWALACH@WEIZMANN.
WEIZMANN.AC.IL

Friday, July 16, 1999

Professor Zvi Artstein
The Vice President for Technology Transfer, here.

re: Division of Royalties on the TBPII agreement with Immunex

Dear Professor Artstein,

To your request, please find enclosed my decision as to the division of royalties on the TBPII agreement of Serono with Immunex.

David Wallach	41.0%
Hartmut Engelmann	33.5%
Dan Aderka	11.5%
Daniela Novick	7.0%
Menahcem Rubinstein	4.5%
Cord Brackebusch	2.5%

It will take much more than a short letter to present all the facts that I considered when making this calculation. Here I just listed, in a succinct manner, the major points of contribution of each of the scientists involved.

David Wallach: I led the study of the TBPs all along. I also led the research on TNF function from which this discovery has emerged. No other research, made by any other group at the Weizmann Institute, can be considered as making a significant contribution to this discovery. In contrast, all the patents related to soluble receptors that have been submitted to Yeda since that time by scientists from the Department of Molecular Genetics have surely emerged from our discovery of the TBPs, and kept gaining from my further studies of this subject.

Hartmut Engelmann: Hartmut did almost all the work involved in the purification of the TBPs. and in clarification of their nature (as soluble TNF receptors). He was also the one that established the immunoassays for the TBPs (with which the work that has led to the 'Autoimmune patent' has been done). His contribution was immense, far beyond that of any student I have ever known. Second to me, he was the leader in this project, contributing ideas, huge work, five years of his life, and exceptional talents.

Dan Aderka: Dan was the first to detect TNF-inhibitory activity in the urine. He partially purified the TBPs and characterized them. He made major contributions (a) to our conclusion that the TNF-inhibitory activity is not a 'Schmutz effect'; (b) to the data of our first application of the TBP patent (the priority document, which was submitted in 1987). In work that Dan has done later on (while being in the States) he contributed to our study of TBPII. Dan also contributed much of the know-how on autoimmune diseases that was the basis for the 'Autoimmune patent'. He also was the one that collected the clinical samples and ran the assays that provided the data that are presented in this patent.

Daniela Novick and Menachem Rubinstein: Daniela and Menachem joined the project at the time in which we had managed already to enrich TBPII. This was done after submission of the priority document and after much of the knowledge of the TBPs had been gained already (including: their activity, the knowledge that they act as cytokine-binding proteins the bioassay by which their purification has been monitored, and detailed knowledge of how to collect, concentrate, and enrich the TBPs in various purification steps, as detailed in claim 8 of the priority document that was submitted before Daniela and Menachem joined the project).

Daniela Novick: Daniela has been a constant companion of Hartmut at the period of the TBP studies and contributed to many aspects of his work.

Menachem Rubinstein: Menachem did not contribute at all to our work on TBPII. He is considered for royalties on the TBPII agreement with Immunex only because of his partial involvement in our work on TBPI (which made only marginal contribution to this deal). In fact, Menachem has not been even aware of our TBPII work at the time of its performance. The first time I brought this study to his attention was when he, as the R&D manager of Interpharm, had to be asked to allow me submitting my paper about TBPII for publication. (Nevertheless, when hearing of the discovery of TBPII, Menachem requested to be a co-author on its publication. Moreover, Professor Meir Wilcheck, who had been asked to advise us about this issue, suggested that I will include him in the TBPII paper. As Meir himself admitted afterwards, this advise was solely for non-scientific considerations).

Cord Brackebusch: Cord did the work and reached the findings that formed the basis for the 'Multimeric' patent. Although he did not have the idea that we patented, his contribution to the findings themselves, as well as to many of the other findings due to which Serono is considered as serious 'player' in the TNF field was immense.

Michel Revel: Michel asks to receive royalties on the TBP patents. This request is completely unfounded. Officially, at the time of the TBP projects Michel was considered as my host. Yet, as Michel himself well knows, this position was by all means fictitious. He had no involvement in my research, neither at the time of the TBP projects, nor in the prior work of my lab, that led to these discoveries. The fact that he 'provided' me with lab space surely cannot be considered as endowing him with patent rights, particularly in view of the fact that, for reasons that I better not go into here, he by all means has owed me this help. I must add that I find the request of Michel rather ironic. Michel himself has never even mentioned my name when considering the royalties about IFN beta; that in spite of the fact that I helped him for years in the projects associated with this IFN.

I thank you for your help,

/s/ David Wallach
David Wallach

EXHIBIT 36

Appendix D

RESEARCH AND DEVELOPMENT AGREEMENT

Made as of the 27th day of December, 1982

BETWEEN

the Government of Israel, on behalf of the State of Israel, represented by the Chief Scientist (the "Chief Scientist") and the Comptroller of the Ministry of Industry and Commerce (jointly hereinafter the "Government")

AND

ISRAEL BIO-ENGINEERING PROJECT, a limited partnership organized and existing under the laws of the State of New York (hereinafter the "Applicant").

WHEREAS, the Applicant wishes to conduct research in the matter of interferons, anti-cellular factors, monoclonal antibodies and nucleic acid segments (hereinafter the "Research"); and

WHEREAS, as used herein, the term "Products" means those items listed in Exhibit A hereto, and which are to be developed by the Applicant; and

WHEREAS, the Applicant wishes to engage Inter-Yeda Ltd., a company duly organized and existing under the laws of the State of Israel (hereinafter the "Developer"), to conduct the Research on behalf of the Applicant so that all the products of the Research, including all the know-how, inventions and patents resulting therefrom will belong to the Applicant; and

WHEREAS, the Government is prepared to take part in the funding of the Research pursuant to the conditions set forth in this Agreement.

NOW, THEREFORE, the parties agree as follows:

1. (a) The preamble to this Agreement comprises an integral part hereof.

* * *

Government, except as to sales and licenses to sell permitted by Subparagraph 7(a) below.

5. (a) The Applicant will be entitled, subject to Paragraphs 6 and 7 below, to exploit all the Research results, including any Patents, in any manner, including the manufacture of Products, granting of licenses, transfer and/or sale of any rights in any matter resulting from the Research.

(b) All income from royalties originating from Patents and/or any other income resulting from the Research will belong to the Applicant, subject to Paragraph 6 below and the Technology Option and Sale Agreement.

6. (a) In the event that the Applicant or Developer does not exploit in Israel the inventions, Patents or other results discovered during the Research or resulting from it or either does not use them commercially in Israel within seven years from the conclusion of the Execution Period (either the original period or as extended, if extended) (hereinafter the Exploitation Period"), the Applicant's rights will be transferred to the Government.

The transfer of the rights to the Government, as specified in this Paragraph 6, shall be an additional guarantee for the Government Loans given by it to the Limited Partners for execution of the Research.

The Applicant does hereby appoint the Government by an irrevocable power of attorney to execute on its behalf all necessary actions, needed to transfer the rights as aforesaid.

(b) The Applicant, either itself or through Developer, will be entitled, at least six months prior to the conclusion of the Exploitation Period, to request the Government to extend the Exploitation Period. The Government will inform the Applicant in writing whether it agrees to the extension of the Exploitation Period, the term of the extension and its conditions. The Government shall have the right, in its discretion, to refuse to grant an extension of the Exploitation Period.

(c) In the event that the Government commercially exploits the Patents under the rights transferred to it pursuant to Subparagraph (a) of this Paragraph, and Profits have been derived from their exploitation or commercial use, then said profits will be applied as follows:

* * *

EXHIBIT 38

[LOGO]

Confidential Private Offering Memorandum

ISRAEL
BIO-ENGINEERING
PROJECT
A New York Limited Partnership

Organized to develop and manufacture in the State of Israel, for sale throughout the world

(1) Human interferons using recombinant DNA techniques
(2) Monocional antibodies for various antigens
(3) Nucleic acid segments
(4) Anti-cellular factors isolated from crude leukocyte interferon preparations

Total Offering

$6,440,000
(161 Units at $40,000 per Unit)
in cash and promissory notes,
and up to an additional

$5,150,000
(approximately $32,000 per Unit)
from the proceeds of
long-term loans to the limited partners
from the Government of Israel.

1982 Financing

Israel D. Rosen & Norman Stein
330 Madison Avenue
NYC 10017 (212) 867-6757

CONFIDENTIAL PRIVATE OFFERING MEMORANDUM

Minimum of 113 and Maximum of 161 Units of

Limited Partnership Interests

of

ISRAEL BIO-ENGINEERING PROJECT

(a New York limited partnership)

Formed to research, develop and manufacture in Israel and sell (i) human interferons produced by recombinant DNA techniques, (ii) monoclonal antibodies for various antigens, (iii) nucleic acid segments, and (iv) anti-cellular factors isolated from crude leukocyte interferon preparations.

The Offering consists of a Minimum U.S. $4,520,000
and a Maximum U.S. $6,440,000
(U.S. $40,000 per Unit)
In Cash and Promissory Notes

Plus up to an Additional Minimum U.S. $3,605,000
and a Maximum U.S. $5,150,000
(Approximately U.S. $32,000 per Unit)
From the Proceeds of Long-Term Loans to Investors
From the Government of Israel

THIS OFFERING INVOLVES
A HIGH DEGREE OF RISK

(see RISK FACTORS)

The offering made hereby expires at midnight New York City time on November 30, 1982, unless extended, or sooner terminated if fully subscribed. If subscriptions for the minimum 113 Units have not been received by the expiration of this offering, no Units will be sold and all funds paid by the subscribers, which will be held in escrow for the account of the Partnership, will be promptly refunded without interest and all notes and related documents will be promptly cancelled and returned.

THIS MEMORANDUM IS FOR USE ONLY BY THE PERSON WHO IS NAMED BELOW AS THE RECIPIENT AND HIS OR HER PURCHASER REPRESENTATIVE(S), IF ANY.

Name of Recipient	Date Received

* * *

may also have their own commercial value, since they are in demand at other academic and commercial laboratories engaged in recombinant DNA research. Dr. Mati Fridkin will head this project.

3. *Anti-Cellular Factors in Crude Interferon Preparations.* Crude leukocyte and lymphocyte interferon preparations contain a number of other proteins, such as lymphokines and other factors shown to have anti-cellular and immunomodulating effects. Because of their anticellular effect, these substances are believed to have potential antitumoral value, and they may prove to be useful in the field of cancer therapy.

Dr. Menachem Rubinstein of the Weizmann Institute has been investigating anti-cellular factors contained in interferon preparations with a view towards concentrating and purifying such factors when they are found. The

Partnership intends to fund Dr. Rubinstein's further research and to clinically test and develop any factors contained in crude leukocyte interferon preparations that are identified as having anti-cellular properties.

4. *Monoclonal Antibodies.* Antibodies are protein molecules produced by certain blood cells. They react specifically with the foreign materials (antigens) that induced their appearance. Antibodies separated from human and animal blood have numerous applications in diagnostic procedures and are a fundamental reagent (antisera) in immunoassay diagnostic systems. Conventional preparations. of antisera comprise the mixture of various antibodies, whereas monoclonal antibodies, which are produced by the hybridomas techniques, represent only a single clone of antibodies and have many advantages compared to conventional antisera. Among other advantages, monoclonal antibodies are highly specific reagents; they are easy to purify and characterize; their production is reproducible, reliable and relatively simple, which eliminates batch-to-batch variations, and they are cost-effective.

Somatic cell hybridoma technology used in the production of monoclonal antibodies represents a specialized approach to genetic engineering. Instead of adding a synthetic DNA fragment to a cell's genetic material, the entire nucleus of a B lymphocyte producing an antibody of desired specificity is inserted into a myeloma cell by cell fusion. This technology has far-reaching applications, not only for analytical and preparative procedures, but mainly for diagnostic uses, in vitro and in vivo, and ultimately as therapeutic tools in medicine.

BBC has estimated worldwide market potential for monoclonal antibodies as $6 million in 1982, increasing to $120 million in 1985 and $250 million in 1988.

Dr. Zelig Eshhar, in collaboration with other scientists at the Weizmann Institute, has been working on the identification, research and development of several specific monoclonal antibodies with potential commercial applications, including antibodies that react with steroid hormones, interferon, tumor antigens and various enzymes. Dr. Eshhar collaborates with several other investigators at the Weizmann institute who are recognized experts in these research fields. The Partnership intends to support Dr. Eshhar's research and to create a hybridoma center, which would develop antibodies in the groups mentioned above for further testing and development. The Eshhar group has already succeeded in developing several antibodies in each such group.

Many companies have begun research and development of various monoclonal antibodies, and some companies have begun production and marketing of them. The Partnership expects very intense competition in the hybridoma area, and many well-funded companies may enter the field. Development and production of the monoclonal antibodies will be fully regulated by the FDA and other regulatory agencies.

The R&D Programs encompass technologies and potential products for use in the medical, pharamaceutical and chemical fields. Most of the Projects will require substantial research, development, testing and appropriate regulatory approvals, which could involve a substantial time period before it will know if any can be commercialized. The Partnership can give no assurances, nor has it received any assurances from Inter-Yeda or Yeda, that any of these products or technologies resulting from the R&D Programs will ever be capable of being commercially developed or will ever generate revenues to the Partnership.

Proposed Budget

The following are estimated budgets for the R&D Programs over their approximate five-year term, assuming sale of the minimum and maximum number of Units. If the number of Units sold is between the minimum and maximum number of Units, each project will be budgeted to receive the minimum amount set forth, and Inter-Yeda will determine the allocation of Offering proceeds in excess of such minimum.

* * *

EXHIBIT 39

Inter-Yeda Ltd.

[Letterhead Omitted In Printing]

December 30th 1982

Israel Bioengineering Project
c/o Mr. Israel Rosen
330 Madison Avenue
New York, New York
U.S.A.

Dear Sirs:

Whereas we entered today into a special research and development agreement and a technology sales agreement with you (hereinafter "the Agreements") we wish to inform you as follows:

1. We believe that there is a significant possibility that patentable inventions may result from the technology to be develpped in the research and development programs as that term is defined in the Agreements.
2. To the best of our knowledge, there are no agreements to which Yeda Research's Development Co. Ltd. or ourselves or any of the scientists to be involved in the research and development programs are a party, relating to the subject matter of the research and development programs other than the pre-existing agreements, and that to the best of our knowledge, none of the pre-existing agreements will have a material, adverse effect on the rights of the partnership as determined in the agreements.
3. We will make our best efforts in order that the scientists engaged in the research and development programs will be involved in no activities competitive therewith which may have material, adverse effects

on the rights of the partnership, during the term of such programs.

4. All the details contained in the Private Offering Memorandum which have been given to you by our company and which relate to the descriptions of our company, to the research and development programs and the [illegible] of the programs are true, complete and accurate to the best of our knowledge.

Yours sincerely,

/s/ Jacob Shalom
/s/
INTER-YEDA LTD.

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ISRAEL BIO-ENGINEERING PROJECT

UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

WESTERN DIVISION

ISRAEL BIO-ENGINEERING PROJECT, Plaintiff and Counterclaim-Defendant, v. AMGEN INC., IMMUNEX CORPORATION, WYETH, WYETH PHARMACEUTICALS, INC., YEDA RESEARCH AND DEVELOPMENT CO., LTD.	Case No. CV 02-6860 RGK (MANx) **DECLARATION OF NEWTON D. BECKER IN OPPOSITION TO YEDA'S MOTION FOR SUMMARY JUDGMENT** **TO BE FILED UNDER SEAL** Date: December 12, 2005 Time: 10:00 a.m.

INTER-LAB LTD., AND SERONO INTERNATIONAL S.A., Defendants and Counterclaim-Plaintiffs.	Ctrm: 850 Before The Honorable R. Gary Klausner
AND RELATED COUNTER-CLAIMS.	

I, NEWTON D. BECKER, declare as follows:

1. I am a limited partner in Israel Bio-Engineering Project (IBEP), a New York limited partnership and the plaintiff in this litigation. I am also the liquidating trustee of IBEP, having been elected to that position in August 1992 by a vote of limited partners in IBEP. I submit this affidavit in opposition to the motion of Yeda Research and Development Company Ltd. (Yeda) for summary judgment. Unless otherwise noted, the facts contained in this Declaration are facts known to me personally as an investor in IBEP and as liquidating trustee of IBEP. If called as a witness, I could competently testify as follows.

2. I have a strong interest in the growth and development of the State of Israel and I have long held the firm belief that Israel's economic development is one of the keys to its future endurance and security. Given this interest and belief, I decided long ago to focus some of my investments in the State of Israel and I found myself one of the first American investors in the Israeli hi-tech industry. Among my investments in the State of Israel was my investment in IBEP, which I made in the initial offering in 1982. I am the single largest investor in IBEP (holding

units constituting over 35% of the amounts raised in the first offering and 25% of the combined offering).

3. Before investing in IBEP, I examined the Private Offering Memorandum (POM) of the partnership, including the proposed Research and Development Agreement, the proposed Sub-Research and Development Agreement (Sub R&D Agreement), and the proposed Technology Option and Sale Agreement (TOS Agreement), among other documents. I went over the POM carefully and in detail before making my investment and it played a significant role in my decision to invest in IBEP the large sum that I paid for my units in IBEP.

4. During the years in which IBEP was being formed, the biotechnological industry had begun developing in the world. In Israel, there was *academic* research in this area but no industrial activity. As an experienced investor in research and development, this state of affairs was known to me at the time I made my investment in IBEP. Then (as now) it was also known to me that the path from scientific discovery to a pharmaceutical product manufactured on an industrial scale is strewn with obstacles. Most products fail. At the time that I invested in IBEP, I was well aware that there is a very long way to go before a product based on a scientific discovery can be sold in commercial quantities, and tens or hundreds of millions of dollars must be invested. Not infrequently, huge investments are lost. Therefore, the money invested at the first stage of research and development is a high-risk investment and is considered "seed money."

5. I understood that my investment in IBEP was just that – seed money – seed money for basic research that could lead to discoveries that could then be further developed

and eventually commercialized by Inter-Yeda over a long period of time, after the expiration of the Research Period in the Sub R&D Agreement. The highly experimental nature of the anti-cellular project in which IBEP was investing was apparent even in the POM, which described the research project, in part, as follows: "Dr. Menachem Rubinstein of the Weizmann Institute has been investigating anti-cellular factors, contained in interferon preparations with a view towards concentrating and purifying such factors when they are found. . . ." (POM at p.38.) As investors, we were informed by the POM that "[m]ost of the projects will require substantial research, development, testing and appropriate regulatory approvals, which could involve a substantial time period before it will know if any can be commercialized." (POM at p.39.)

6. In short, I well understood that my investment in IBEP could result in a huge loss and that any scientific discovery made during the Research Period could require years of additional work in order to prepare it for the commercial market. But I also well understood that if any scientific discoveries were made during the Research Period in the Sub R&D Agreement, IBEP would continue to own those discoveries, including patents and commercial products resulting from those discoveries. This was so even though Inter-Yeda (which, under the TOS Agreement, was granted a product license on all discoveries with an option to purchase) might do the additional development that would be necessary to commercialize the discovery.

7. My understanding is reflected in the various agreements. The TOS Agreement, for example, expressly anticipated and provided that Inter-Yeda could conduct "Additional Research and Development" on IBEP's "Proprietary Information . . . after the term of the Sub R&D

Agreement." (TOS Agreement ¶ 9.) The TOS Agreement explained that IBEP's "Proprietary Information" included "[a]ny and all inventions, patent applications, patents (wherever applied for or granted), trade secrets, technical information . . . and other technology or know-how developed in the R&D Programs." (TOS Agreement ¶ 1(d).)

8. The TOS Agreement also provided that IBEP would be entitled to payments in the form of licensing fees on sales of any discoveries that were eventually commercialized, which emphasized that IBEP owned the discoveries and simply permitted Inter-Yeda to do additional research and development on them: "If after the termination of the Sub R&D Agreement and during the term hereof, any Product is Reduced to Practice or if a patent application is filed with respect thereto, the Partnership shall be entitled to Payments with respect to Net Sales or License Fees in respect thereof. . . ." (TOS Agreement ¶ 9(b).)

9. The Sub R&D Agreement, among other documents, made clear that all of the scientific discoveries were the sole property of IBEP and that although Inter-Yeda could include the names of individual inventors on any patent registrations, no proprietary rights would be vested in those individuals: "Subject to the provisions of the TOS Agreement, any and all of the Proprietary Information shall become the sole property of [IBEP]. . . . Nothing contained herein shall prevent [Inter-Yeda] from including in any patent registration the name(s) of the individual inventor(s) as required by law, provided that no proprietary rights are vested in such individuals." (Sub R&D Agreement ¶ 10(A).)

10. These provisions of the TOS Agreement and the Sub R&D Agreement confirm my understanding of the Agreements – that is, that IBEP would *not* be divested of its ownership of the 701 patent simply because Prof. Menachem Rubinstein performed some additional development work after the discovery, which was necessary to commercialize the discovery, or because Prof. Rubinstein's name appears as an inventor of the 701 patent.

I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge.

Executed on November 23, 2005, at Los Angeles, California.

/s/ Newton D. Becker
Newton D. Becker

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Intervenor-Counterclaimant YEDA RESEARCH
AND DEVELOPMENT COMPANY LTD.

UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

ISRAEL BIO-ENGINEERING PROJECT,) Case No. CV 02-6860 RGK (MANx)
)
Plaintiff,) **DEFENDANT YEDA'S COUNTERSTATEMENT OF UNCONTROVERTED FACTS**
vs.)
AMGEN, INC., et al.,)
)
Defendants.) **TO BE LODGED**

AMGEN, INC., et al.,
Counterclaim-Plaintiffs,
vs.
ISRAEL BIO-ENGINEERING PROJECT,
Counterclaim-Defendant.

UNDER SEAL
Date: December 12, 2005
Time: 10:00 A.M.
Crtrm: Hon. R. Gary Klausner, 850

* * *

2. As an Inter-Yeda Employee, Menachem Rubinstein Performs Additional Work to Purify and Sequence TBP-1

	IBEP'S ADDITIONAL MATERIAL FACTS		YEDA'S RESPONSE
75.	From August 1987 to 1990, Menachem Rubinstein was the R&D Manager of and Chief Scientist of InterPharm, the parent company of Inter-Yeda. Depo. at 15, Ex. 24	75.	Undisputed.
76.	As of August 20, 1987, Rubinstein was working "full" time at Inter-Yeda, excluding one workday per week. 8/20/87 Employment Agreement between InterPharm and Rubinstein, Ex. 49.	76.	It is undisputed that Rubinstein's employment agreement with InterPharm provides that he will "work at InterPharm full time, except for one day a week (meaning at least 36 hours a week), the rest of your leisure time you will be permitted to engage in your

			academic occupations at the Weizman Institute of Science. Employment Agreement between InterPharm and Rubinstein Ex. 49.
77.	Rubinstein first reviewed Israeli no. 83878 in September 1987, in his capacity as the InterPharm R&D Manager. Rubinstein Decl. ¶ 5; Rubinstein	77.	Undisputed.

* * *

EXHIBIT 45

Inter-Yeda Ltd. **Inter-Yeda Ltd.**

July 5, 1987
EG/20/670

To
Professor David Wallach
Inter-Yeda Ltd.
Kiryat Weizmann
Ness Ziona

Approved / Wallach

Dear Professor Wallach:

You recently provided us with results of a study you conducted on the raw protein factor in urine (*CUF*) that is active against *TNF*. These results are, indeed, only initial ones and it appears that a great deal of work and a considerable investment will be necessary in order to continue their development. But this is the appropriate time to remind you that as an employee of Inter-Yeda, starting January 1, 1985, the results of research performed by you from that date onwards are owned in their entirety by Inter-Yeda, and it has the exclusive right to use them in any manner. Additionally, you are not permitted to contact any other entity in regards to those research subjects and not even to publicize, whether orally or in writing, any result or data related to these subjects without prior permission from Inter-Yeda. Moreover, these same obligations apply as well on every researcher and doctoral student working with you on these research subjects.

Inter-Yeda has an interest in the raw factor from urine and we will shortly submit a patent application to the Israel Patent Office, based on the document that you presented to us last month.

Having said that, since there is no financing at all this year for this subject within the framework of these projects at the Weizmann Institute, the company has decided to transfer the project into its own hands and to continue the development of the project within the confines of its own building in Kiryat Weizmann. You are therefore requested to transfer the *CUF* project with all its findings and results to Dr. Eichanan Ezra at Inter-Yeda by the end of July 1987. Within the framework of your continued employment in the company until the end of 1987, we request that you serve as the company's consultant in this matter and in every other subject on which you worked in the past within the framework of the company's projects. As far as the continuation of activity in 1988, we need to discuss that matter. Should you decide to transfer to some academic institution, we would be pleased to discuss with you continued cooperation whatever framework you find yourself in.

Clarification of these matters is necessary in light of the information provided me by the President of the Institute and his deputy during my visit with them on April 21, 1987, based on which they see you as a regular employee of Inter-Yeda, and your present work, with all its endeavors, as an endeavor of Inter-Yeda that may not even be housed at the Institute.

Science Based Industrial Park, Kiryat Weizmann, 76 110, Ness-Ziona. Telephone: 08-475 786 Telex: 361953 IPL IL Facsimile: 08-465-566

SCIENCE BASED INDUSTRIAL PARK,
KIRYAT WEIZMANN, NESS-ZIONA 76 110, ISRAEL.
PHONE: 08-475 786 TELEX: 361953 IPL IL
FAX: 08-465 566

Inter-Yeda Ltd. **Inter-Yeda Ltd.**

I would appreciate your confirmation and agreement of the contents of this letter of mine.

Sincerely
E. Geller
Dr. Ehud Geller
General Manager, Inter-Yeda, Ltd.

I confirm and accept the contents of this letter.

July 7, 1987 *David Wallach*
Date Professor David Wallach

Science Based Industrial Park, Kiryat Weizmann, 76 110, Ness Ziona. Telephone: 08-475 786 Telex: 361953 IPL IL Facsimile: 08-465 566

SCIENCE-BASED INDUSTRIAL PARK,
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EXHIBIT 25

[LOGO]

Appendix E

SUB-RESEARCH AND DEVELOPMENT AGREEMENT AND PROPOSED FORM OF AMENDMENT THERETO

PROPOSED FORM OF

SUB-RESEARCH AND DEVELOPMENT AGREEMENT

THIS AGREEMENT made as of this 30th day of December 1982, by and between ISRAEL BIO-ENGINEERING PROJECT, a limited partnership organized and existing under the laws of the State of New York (the "Partnership"), and INTER-YEDA LTD., a company organized and existing under the laws of the State of Israel ("Developer").

WHEREAS, the Partnership desires to conduct the research and development programs (hereinafter referred to as "the R&D Programs") referred to in the Development Plan attached to the Research and Development Agreement of even date herewith (the "R&D Agreement"), between the Partnership and the Government of Israel, represented by the Office of the Chief Scientist and Comptroller of the Ministry of Industry and Commerce (the "Government"), to conduct the R&D Programs and in respect thereof, to report directly to the Office of the Chief Scientist of the Ministry of Industry and Commerce (the "OCS"); and

WHEREAS, Developer has entered into the Yeda Agreements (as defined below) with Yeda Research and Development Company Ltd. ("Yeda"), by which Yeda has undertaken to carry out research and development in accordance with the R&D Programs and the Yeda Agreements; and

WHEREAS, the Partnership desires to engage Developer to conduct the R&D Programs in cooperation with Yeda; and

WHEREAS, Developer desires to be engaged by the Partnership for the purpose of conducting the R&D Programs in cooperation with Yeda; and

WHEREAS, Developer and the Partnership are signing a Technology Option and Sale Agreement contemporaneously herewith (the "TOS Agreement"); and

WHEREAS, by Confidential Private Offering Memorandum dated October 5, 1982 (the "Memorandum"), the Partnership is offering a minimum of 113 Units and a maximum of 161 Units of limited partnership interests in the Partnership for a minimum total of $7,990,000 and a maximum total of $11,395,000 of which $40,000 per Unit will be in the form of subscription payments by the limited partners (the "Limited Partners") and approximately $31,000 per Unit will be contributed by the Limited Partners as additional capital to the Partnership from the proceeds of loans made to them by the Government (the "Government Loans") through the Industrial Development Bank of Israel Limited (the "Bank") equaling approximately $32,000 per Unit reduced by the 1% OCS Financing Fee and the 3% Loan Placement Fee (as those terms are defined in the Memorandum), pursuant to the Loan Agreement substantially in the form of Appendix C to the Memorandum (the "Loan Agreement"), and loans (the "Bridge Loans") made to the Limited Partners by The North American Bank Ltd. in Israel or any other bank

("NAB") pursuant to a short term revolving credit agreement (the "Credit Line Agreement") substantially in the form of Appendix I to the Memorandum.

NOW THEREFORE, in consideration of the mutual covenants herein contained, the parties hereto mutually agree as follows:

I. CERTAIN DEFINITIONS

A. As used herein, the term "Products" means Products, as that term is defined in Exhibit I attached hereto. For the purpose of removing doubt, it is agreed that the term "Products" shall not include any item that has been Reduced to Practice prior to the date hereof.

B. As used herein, the term "Pre – existing Technology" shall mean the knowhow and technology directly relating to the R&D Programs that is presently in the possession of or under the control of Developer or Yeda.

C. As used herein, an "Affiliate" of, or a party "affiliated" with a specified party, is a party that directly or indirectly through one or more intermediaries, controls or is controlled by, or is under common control with, the party specified. In this connection, control of a corporate entity shall mean the power to elect 50% or more of the Board of Directors thereof.

D. As used herein, the term "Yeda Agreements" means the agreements specified in Exhibit 2 attached hereto and any amendments thereof consented to by the Partnership, which consent shall not be unreasonably withheld.

E. As used herein, "Proprietary Information" means any and all inventions, patent applications and patents (wherever applied for or granted), trade secrets, technical information (including all blueprints, plans, workbooks, drawings, specifications, formulas and processes) and other technology or knowhow developed in the R&D Programs. The Proprietary Information shall not include Pre-existing Technology, any technical information or knowhow relating to a Product which is not patented or patentable and which is described in any prior printed publication or is publicly known in the medical products industry, or any technology which is solely related to an Accidental Discovery.

F. As used herein, "Accidental Discovery" means any and all technology which is wholly unrelated to any Product and which was developed serendipitously in the R&D Programs.

G. As used herein the term "Reduced to Practice" means in respect of any Product the earlier of:

(1) the date on which Developer has brought its research to such stage that:

(i) the Product is being produced and is reproducible on a pilot scale basis from which industrial scale-up can be reasonably contemplated; and

(ii) the basic requirements for the possible use of the Product with regard to safety, toxicity and efficacy are being met; *or*

(2) the first date on which Yeda or Developer or their nominee has applied to the relevant health authorities in one of:

(i) United States

(ii) Great Britain

(iii) Italy

(iv) Germany

(v) France

for approval to commercially exploit such Product.

II. DEVELOPER REPRESENTATIONS AND WARRANTIES

Developer represents, warrants and covenants that:

A. It has provided true and complete copies to the Partnership of all the pre-existing agreements, as amended, which have been given to it by Yeda, by the Weizmann Institute or by the Chief Scientific Investigators, as that term is defined in the Yeda Agreements, and that relate to the subject matter of this Agreement.

B. To the best of its belief, there are no other preexisting agreements relating to the subject matter of this Agreement.

C. To the best of its belief, the Partnership will not be adversely affected in any material way on account of the existence of any patents or trade secrets held by any third parties known to Developer.

D. No investigation by the Partnership relating to the subject matter of Subparagraphs A, B and C of this Paragraph II shall in any way diminish Developer's responsibility for the accuracy and completeness of the foregoing representations and warranties.

E. The entire proceeds of all payments by the Partnership hereunder to Developer will be used to develop the Products and no portion thereof will be expended for ordinary testing or inspection of materials or products for quality control, other than in connection with the development of the Products in the R&D Programs, nor for efficiency surveys, management studies, consumer surveys, advertising promotions or the like. Developer also covenants that all of the technology for which payment is made to Developer by the Partnership hereunder will be created or developed solely in the R&D Programs. The representations made in this subparagraph E. shall survive the termination of this Agreement for any reason.

III. SPECIFIC SERVICES

A. Developer shall immediately commence the R&D Programs, which it shall conduct hereunder in accordance with the initial application heretofore submitted to the OCS and otherwise in accordance with this Agreement, the Yeda Agreements, the R&D Agreement and any further research and development agreements contemplated for the completion of the R&D Programs (the R&D Agreement and all such future research and development agreements are sometimes hereinafter collectively referred to as the "Program Agreements"), and any other plans, Specifications or proposals that may hereafter be submitted to, and approved by, the OCS during the term of this Agreement; provided, however, that nothing contained herein shall obligate Developer to commence the R&D Programs until the Partnership makes the first payment required under this Agreement.

B. If any Products are in fact developed, Developer shall endeavor to continually improve such Products during the term of this Agreement.

IV. R&D AGREEMENT WITH STATE OF ISRAEL

A. Developer specifically agrees to perform all undertakings and responsibilities of the Partnership as provided in Paragraphs 2(c) through (h), 4, 6, 7, 8, and 12 of the R&D Agreement and to perform all Developer's undertakings and responsibilities pursuant to this Agreement and the Program Agreements unless the Partnership:

(i) shall fail to make any of the payments pursuant to Article V hereof; or

(ii) shall be in default under this Agreement, the TOS Agreement, the R&D Agreement or the Loan Agreement and shall not have cured such default after Developer gives 60 days prior notice thereof to the Partnership, unless such default is caused by the default of Developer.

B. This Agreement and all its terms shall automatically apply to all subsequent R&D Agreements entered into by the Partnership with the Government and relating to the R&D Programs.

V. R&D PROGRAM EXPENDITURES

A. (1) The total amount to be expended for the R&D Programs shall be between $7,000,000 and $10,000,000, such amount to be determined by the proceeds of the Offering. Subject to the Partnership's continuing receipt of the capital contributions (the "Capital

Contributions") required to be made by its Limited Partners in accordance with the terms of payment for limited partnership interests contemplated by the Memorandum and, more particularly, the form of Subscription Agreement included in the Memorandum as Appendix A, and the cash flow projections referred to in Appendix H of the Memorandum (the "Cash Flow Projections") (including those Capital Contributions to be made from the proceeds of the Government Loans and the Bridge Loans), the Partnership agrees to pay Developer between $7,000,000 and $10,000,000, the exact amount to be determined by the proceeds of the Offering, in installments against and immediately upon the receipt of telephonic or other advice from Developer confirming the transmission to the Partnership of vouchers evidencing services rendered to the Partnership or expenses of the R&D Programs, that have been approved by the OCS, and against 50% of which vouchers Government Loans are simultaneously being made by the Bank pursuant to the Loan Agreement. Notwithstanding the foregoing, the Partnership shall pay the first installment contemporaneously with and in the same amount as the First Advance is made under the Loan Agreements. In this connection, the Partnership agrees to deposit in an account maintained by the Partnership at NAB within 15 days after receipt by the Partnership of the Capital Contributions, the net proceeds of such Capital Contributions after deduction of all expenses or reserves therefor, other than "Research and Development Expenses", that are anticipated by and projected in the Cash Flow Projections.

(2) The entire proceeds of the Government Loans, reduced by the 1% OCS Financing Fee and 3% Loan Placement Fee, will be paid by the Partnership to Developer in

accordance with the provisions of the immediately preceding paragraph.

(3) The obligation of Developer to perform its obligations hereunder is subject to its receipt of the amounts set forth in this Section V.A.

(4) By December 15, 1985, Developer shall submit to the Partnership a proforma invoice for the R&D Programs expenditures for the 1986 calendar year, which invoice will be due December 31, 1985.

B. In the event that the OCS shall refuse to authorize any further disbursements whatsoever to the Limited Partners pursuant to the Loan Agreement, and such refusal shall continue for a period of 60 days following written notice thereof to Developer, the Partnership shall have the right and option to terminate this Agreement. In addition, the obligation of the Partnership to make any further payments hereunder or to deposit funds with NAB, and the obligation of Developer to perform services hereunder shall be suspended during any period when, for any reason whatsoever, the OCS refuses to authorize any further disbursements to the Limited Partners pursuant to the Loan Agreement and such refusal shall be continuing. To the extent the Partnership shall have paid to Developer out of the Limited Partners' subscription payments (excluding the Government Loan) an amount in excess of the amount the OCS authorized the Bank to lend pursuant to the Loan Agreement, then such excess amount paid by the Partnership to Developer shall be deemed a loan repayable upon demand.

VI. SUBMISSION OF AND COMPLIANCE WITH PLANS AND BUDGETS

Developer agrees to use its best efforts to conduct the R&D Programs during the term of this Agreement according to the Development Plans and Detailed Budgets referred to in the R&D Agreements. In this connection, Developer hereby agrees that the annual detailed budget submitted to the OCS will provide for the "research and development expenses" during calendar years 1982, 1983, 1984, 1985 and 1986 aggregating 1,800,000, 1,700,000, 1,700,000, 1,000,000, and 800,000, respectively, as set forth in the Cash Flow Projections if the minimum number of Units is sold, or 2,000,000, 2,250,000, 2,250,000, 2,000,000, and 1,500,000, respectively, if the maximum number of Units is sold, In the event a number of Units between the minimum and maximum is sold, Developer agrees that the amount provided for "research and development expenses" in the aforesaid annual detailed budget shall bear substantially the same ratio to the respective amounts set forth in the preceding sentence with respect to the sale of the minimum number of Units, as the number of Units, sold bears to such minimum number.

VII. ECONOMIC RISK

The Partnership acknowledges that the results of the R&D Programs cannot be predicted or guaranteed in any manner and that Developer makes no guarantees or representations as to obtaining a positive end result. Developer will, however, under the terms of this Agreement, use its best efforts to achieve commercially feasible Products within the Execution Period referred to in the R&D Agreement.

VIII. ACCESS TO INFORMATION

A. Subject to the terms of the R&D Agreement, the General Partners of the Partnership, or its duly authorized representative, and the Government shall be permitted access during normal business hours to the premises at which the R&D Programs are being conducted for the purpose of monitoring the progress of the R&D Programs, provided prior written approval for such access is obtained from Developer, which approval shall not be unreasonably withheld.

B. Developer shall keep full and complete records, notes and workbooks containing all experiments performed during all phases of the R&D Programs and the results thereof, and such other documentation as the Government may require. Developer shall provide the Partnership, concurrently with reports to the Government, but not less frequently than semi-annually, brief technical reports on the progress of the R&D Programs and such other' information as the General Partners of the Partnership may reasonably request.

IX. PATENTS

A. On behalf of the Partnership, Developer shall apply for and obtain patents in Developer's and/or Yeda's name(s) on all inventions resulting from the R&D Programs which Developer, in its sole discretion, considers advisable to apply for and obtain; provided, however, that the beneficial ownership of all rights, title and interest in and to such patents and patent applications that form a part of the Proprietary Information shall be and hereby are assigned to the Partnership from the date the Partnership shall have made the first payment to the Developer pursuant to this Agreement in perpetuity, unless and until the Developer shall have purchased the Proprietary Information in respect thereof according to the provisions of the TOS Agreement.

B. The OCS has allocated and approved amounts for purposes of registration and patent applications, which amounts Developer believes are sufficient for these-purposes. Any additional amounts that will be required toward the cost of all patent applications and the processing thereof, including legal fees shall be borne by the Developer; provided, however that the Partnership shall reimburse the Developer for up to 50% of such patent costs and fees expressed in U.S. dollars at the date such costs and fees have been incurred, which reimbursement shall be made out of payments to be received by the Partnership from Developer in accordance with the provisions of the TOS Agreement, but such reimbursements shall not exceed $7,500 per year or an aggregate of $30,000.

X. PROPERTY RIGHTS

A. Subject to the provisions of the TOS Agreement, any and all of the Proprietary Information shall become the sole property of the Partnership. Subject to the provisions of Paragraph IX above regarding the registration of patents in Developer's and/or Yeda's name(s), Developer shall assign to the Partnership all its rights, title and interest in and to the Proprietary Information and shall require all persons employed by it, presently or in the future, to do the same unless and until Developer shall become the owner of all of the Partnership's rights, title and interest in and to the Proprietary Information in accordance with the TOS Agreement. Nothing contained herein shall prevent Developer from including in any patent registration the name(s) of the individual inventor(s) as required by law, provided that no proprietary rights are vested in such individuals.

B. Developer hereby grants the Partnership a royalty free, non-exclusive license to use the Pre-existing Technology for purposes of conducting the R&D Program only. In this connection, Developer represents and warrants to the Partnership that Developer has all the requisite authority, rights and power to grant such license.

C. The Partnership hereby grants Developer a non-exclusive license (with the right to sublicense) in perpetuity, to use the Proprietary Information for any purpose that is unrelated to the development, improvement, use, manufacture, sale, distribution, lease or license of any Product or component thereof that has a chemical formulation substantially similar to, or is of the same chemical family as, any of the Products. Such license shall survive the termination for any reason of this Agreement.

XI. TERM

A. This Agreement shall be effective for a period coterminous with the longer of the Execution Period as defined in the R&D Agreement or any analogous period referred to in any other Program Agreement.

B. The Partnership may, in its discretion, terminate this Agreement, on 30 days written notice, in the event that:

(1) Developer commits a fundamental breach of the provisions of any Program Agreement or this Agreement and such breach by Developer continues for a period

of 60 days after written notice thereof by the Partnership to Developer;

(2) Developer voluntarily commences bankruptcy, insolvency, reorganization, rearrangement, receivership, dissolution, liquidation or any similar proceedings;

(3) Developer is adjudicated insolvent or bankrupt,

(4) Developer has all or a substantial portion of its assets expropriated by any government;

(5) Developer is dissolved or liquidated; or

(6) Interpharm Laboratories Ltd. becomes the owner of less than 25% of the equity of Developer.

C. If one of the "Chief Scientific Investigators," as such term is defined in the Yeda Agreements, ceases to supervise that part of the R&D Program of which he is the head, then the Partnership may, at its discretion, terminate this Agreement only insofar as that particular R&D Program is concerned; except that for the purposes of this Article XI.C., Dr. Fridkin's research shall be considered to be a part of the research of Prof. Revel and only the cessation of the supervision of Prof. Revel shall be grounds for exercise of the right to terminate the R&D Programs supervised by Prof. Revel and Dr. Fridkin.

D. Developer may, in its discretion, terminate this Agreement, on 30 days written notice, in the event that the Partnership:

(1) commits a fundamental breach of any of its obligations hereunder (other than a breach which is caused by any action or inaction by Developer) and such

breach continues for a period of 60 days after written notice thereof by Developer to the Partnership;

(2) voluntarily commences bankruptcy, insolvency, reorganization, rearrangement, liquidation, dissolution, receivership or any similar proceedings;

(3) is adjudicated insolvent or bankrupt;

(4) has all or a substantial portion of its assets expropriated by any government;

(5) is dissolved or liquidated; or

(6) fails to make any payment to Developer when due for a period of 60 days following written notice of such failure from Developer to the Partnership; provided such failure results from the refusal of the OCS to authorize disbursement of the Government Loans for reasons other than Developer's breach of this Agreement, the R&D Agreement or any Program Agreement.

XII. NON-ASSIGNABLE

Neither party shall assign this Agreement without the consent of the other. This Paragraph shall not limit the Partnership's rights to require Inter-Yeda to assign its rights hereunder to a third party or prevent the Partnership from being assigned Inter-Yeda's rights under any Yeda Agreement.

XIII. NOTICES

Any notices or other communication required or permitted to be given to either party under this Agreement shall be given, in writing, by cable, hand delivery or registered air mail, postage prepaid, addressed to each party at the following addresses:

If to the Partnership: Israel Bio-Engineering Project
c/o Israel D. Rosen and
Norman Stein
330 Madison Avenue
New York, New York 10017

With a copy to: Burns Summit Rovins & Feldesman
445 Park Avenue
New York, New York 10022
Attention: Samuel F. Ottensoser, Esq.

If to Developer: Inter-Yeda Ltd.
Kiyat Weizmann
Nes Tsiona, Israel

With a copy to: David Efrati, Esq.
Rafael and Efrati
Shalom Tower, 9 Ahad Haam St.
Tel Aviv, Israel

Notices shall be deemed to have been received on the date of hand delivery, or two days after the date of cabling or 10 days after the date of mailing, as the case may be.

XIV. CONFIDENTIALITY AND SECURITY

Subject to the terms of Section 13 of the Yeda Agreements, the parties hereto each agree to use their best efforts to keep the Proprietary Information confidential except for the purpose of furthering the interests of the Partnership in the R&D Programs and pursuant to the TOS Agreement and the license granted to Developer pursuant to Article X.C. hereof; provided that nothing contained herein shall prevent disclosure of anything which is described in any prior printed publication available to public inspection or anything publicly known in the industry in which the Partnership or Developer is engaged, or disclosure to the Government of any information which shall be required by the Government. The Partnership and Developer shall each require their employees, agents, Affiliates, subcontractors, sublicensees, other licensees and others who will properly have access to the Proprietary Information through the Partnership and Developer, respectively, to first enter into appropriate non-disclosure agreements requiring them to maintain the confidentiality contemplated by this Agreement in perpetuity.

XV. EXCLUSIVITY

Developer shall not engage, directly or indirectly, in any research and development activities for the purpose of developing any Products for any party other than the Partnership during the term of this Agreement.

XVI. FORCE MAJEURE

No party to this Agreement shall be liable for delay in the performance of any of its obligations hereunder if such delay is due to causes beyond its reasonable control, including but not limited to, acts of God, fires, strikes, acts of war, or intervention by any governmental authority, but any such delay or failure shall be remedied by such party as soon as possible.

XVII. RELATIONSHIP OF THE PARTIES

In no event shall this Agreement be construed to create a partnership, joint venture or general agency relationship between Developer and the Partnership. It is the specific intention of the parties that Developer be considered to be an independent contractor and hired. for the services to be rendered hereunder.

XVIII. INTER-YEDA BREACH

The provisions of subparagraph 22(b) of the TOS Agreement shall apply to this Agreement *mutatis mutandis.*

XIX. GOVERNING LAW

This Agreement and the rights of the parties hereunder shall be governed, by and construed in accordance with the laws of the State of Israel.

XX. SEVERABILITY

If any provision in this Agreement is held by a court of competent jurisdiction to be invalid, void or unenforceable, the remaining provisions shall, nevertheless, continue in full force without being impaired or invalidated in any way.

XXI. INJUNCTIVE RELIEF

Each of the parties hereto acknowledges that its failure to comply with any of the terms of this Agreement could cause irreparable damage to the other. Accordingly, in the event of a breach by either of the parties hereto of, any of the provisions of this Agreement, the other party shall have the immediate right to secure an order enjoining such breach; and if this Agreement has been terminated, the breaching party may be enjoined from any continued operation or breach of this Agreement. This covenant shall be enforce-able notwithstanding any rights that the parties may otherwise have.

XXII. CONDITION SUBSEQUENT TO EFFECTIVENESS

This Agreement has been executed and delivered by the parties upon the understanding that it shall become null and void and of no further force and effect whatsoever (and in such event neither the Partnership nor the General Partners, individually, or as General Partners, shall have any liability whatsoever to Developer) if the Partnership shall have received by December 31, 1982 less than $4,520,000 in cash and principal amount of promissory notes from subscribers for limited partnership interests of the Partnership in accordance with the offering by the Partnership pursuant to the Memorandum.

XXIII. ENTIRE AGREEMENT

Except as specifically referred to herein, this Agreement constitutes the entire agreement between the parties, and supersedes and abrogates any prior agreements or understandings between the parties with respect to the subject matter of the R&D Programs.

XXIV. AMENDMENTS

No amendment or change hereof or addition hereto shall be effective or binding on either party unless set forth in writing and executed by a duly authorized representative for each party.

XXV. BINDING EFFECT

This Agreement shall inure to the benefit of and be binding upon the parties hereto and their successors and, if permitted, their assigns.

XXVI. COUNTERPARTS

This Agreement may be executed in any number of counterparts, each of which when so executed shall be deemed to be an original and all of which when taken together shall constitute one agreement.

XXVII. YEDA AGREEMENTS

A. Developer agrees that it will not terminate the Yeda Agreements without the consent of the Partnership. Notwithstanding the foregoing, such consent will not be required in the event that Developer terminates this Agreement on account of the Partnership's breach.

B. In the event Inter-Yeda breaches any Yeda Agreement in such manner that Yeda shall be entitled to terminate such Yeda Agreement, then the Partnership shall have the right to cure such breach or breaches after giving Inter-Yeda 30 days notice of its intention to cure, or such shorter notice period as may be necessary or reasonable to allow the Partnership to cure such breach within the period provided in Section 17F of the Yeda Agreements, and upon such cure, Inter-Yeda shall assign all its rights under the breached Yeda Agreement to the Partnership and shall, on request by the Partnership, assign its rights hereunder to any party acceptable to Yeda, after which time Inter-Yeda shall have no further rights hereunder. This subparagraph XXVII. B. shall have no application if

Inter-Yeda's breach of such Yeda Agreement is caused solely by the breach by the Partnership of this Agreement or the TOS Agreement that would entitle Inter-Yeda to terminate such agreement.

IN WITNESS WHEREOF, the parties have executed this Agreement as of the date first above written.

ISRAEL BIO-ENGINEERING PROJECT

By: /s/ Israel Rosen
General Partner

INTER-YEDA LTD.

By: /s/ Israel Makob
[Illegible]